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(Additional counsel on following page)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

In Re 2025 Children's Hospital of Los Angeles Subpoena	Case No.: _____ CLASS ACTION **EXHIBITS 8-13 IN SUPPORT OF MOTION TO QUASH; MOTION TO PROCEED UNDER PSEUDONYM; AND MOTION FOR CLASS CERTIFICATION**

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**Pro hac vice application forthcoming*

EXHIBIT 8

EXHIBIT 1

UNITED STATES OF AMERICA
DEPARTMENT OF JUSTICE

SUBPOENA DUCES TECUM

No. 25-1431-019

To: The Children's Hospital Corporation d/b/a Boston Children's Hospital
300 Longwood Avenue
Boston, Massachusetts 02115

YOU ARE HEREBY COMMANDED TO APPEAR BEFORE Patrick Runkle, Ross Goldstein, and/or Francisco Unger, officials of the United States Department of Justice, and you are hereby required to bring with you and produce the following:

Please see Attachment A

which are necessary in the performance of the responsibility of the United States Department of Justice to investigate Federal health care offenses as defined in 18 U.S.C. § 24(a).

Please contact Assistant Director Patrick Runkle, Assistant Director Ross Goldstein, or Trial Attorney Francisco Unger at 202-616-0295 if you have any questions regarding this Subpoena Duces Tecum.

PLACE AND TIME FOR APPEARANCE:

U.S. Department of Justice, Consumer Protection Branch, 450 Fifth St., NW, Washington, D.C., on Wednesday, the 9th day of July, 2025, at ten o'clock a.m.

Failure to comply with the requirements of this subpoena will render you liable to proceedings in the district court of the United States to enforce obedience to the requirements of this subpoena, and to punish default or disobedience.

Issued under authority of Section 248 of the Health Insurance Portability & Accountability Act of 1996, Public Law No. 104-91 (18 U.S.C. § 3486)

IN TESTIMONY WHEREOF

Brett A. Shumate, Assistant Attorney General, the undersigned official of the United States Department of Justice, has set his hand this 11th day June, 2025.

BRETT SHUMATE

Digitally signed by BRETT SHUMATE
Date: 2025.06.11 12:04:06 -04'00'

(signature)

RETURN OF SERVICE

I, being a person over 18 years of age, hereby certify that a copy of this subpoena was duly served on the person named herein by means of:

1. Personal delivery to an individual, to wit:

(name)

(title)

(address)

2. Personal delivery to an address, to wit:

(description of premises)

(address)

3. Registered or certified mailing to:

(name)

(address)

At _____ a.m. | p.m. on

(date)

(signature)

(title)

UNITED STATES OF AMERICA
DEPARTMENT OF JUSTICE

SUBPOENA DUCES TECUM

Upon contumacy or refusal to obey, this subpoena shall be enforced by order of the appropriate United States District Court.

Case 2:25-cv-11163-SJM-APP ECF No. 1-1, PageID.9 Filed 05/21/25 Page 9 of 10

ATTACHMENT A TO SUBPOENA TO:

THE CHILDREN'S HOSPITAL CORPORATION d/b/a BOSTON CHILDREN'S HOSPITAL
300 LONGWOOD AVENUE
BOSTON, MASSACHUSETTS 02115

I. DEFINITIONS

1. "You," "Your Company," and "the Company," means:

   a. The Children's Hospital Corporation d/b/a Boston Children's Hospital, a Massachusetts corporation, whose principal place of business is located at 300 Longwood Avenue, Boston, Massachusetts, without regard to any name under which it has done business;

   b. All of its predecessors, subsidiaries, affiliates, branches, divisions, groups, business units, business segments, operations, units, parent organizations, successors, assigns, plants, and any joint ventures of which they were or are a part, including, without limitation, the Gender Multispecialty Service at Boston Children's Hospital; and

   c. Each of its present or former officers, directors, employees, attorneys, representatives, and agents acting or purporting to act or appearing to act on behalf of the Company, whether or not acting within the proper scope of his or her actual authority.

2. "Employee" means any person including, but not limited to, any independent contractor or agent, all past and present directors, officers, agents, representatives, attorneys, accountants, advisors, and consultants who acted or purported to act on behalf of the Company or who have performed any service for the Company or under its name, whether on a full-time, part-time, piece-work, commission, volunteer, or other basis, and whether paid or unpaid.

3. "Document" should be afforded the broadest possible meaning and includes every writing or record of whatever type or description, including but not limited to any electronically stored data or paper document, in the possession, custody, or control of the Company. This includes, but is not limited to:

   a. All material that is handwritten, typed, printed, recorded, transcribed, taped, filmed, in graphic form, or in aural form;

b. Drawings, designs, manuals, memoranda, emails, reports, financial reports, notes, diaries, notations of any sort of conversations, working papers, letters, envelopes, telegrams, messages, studies, analyses, books, articles, notebooks, booklets, circulars, bulletins, notices, instructions, pamphlets, pictures, films, videos, voice recordings, maps, work papers, arithmetical computations, calendars (including electronic calendars), date books, task lists, minutes, all communications of any type (e.g., e-mail, voice mail, text messaging, WhatsApp and similar applications), social media content (including posts, messages, comments, and metadata), audio and video files,

c. Electronically stored data on magnetic or optical storage media as an "active" file or files (readily readable by one or more computer applications or forensics software), including metadata;

d. Any electronic files saved as a backup, including metadata;

e. Any deleted but recoverable electronic files, including metadata;

f. Any electronic file fragments (files that have been deleted and partially overwritten with new data), including metadata;

g. Every copy of every document where such copy is not identical to the original because of any addition, deletion, alteration, or notation; and

h. All attachments, enclosures, or other matter affixed to, transmitted with, or incorporated by reference within documents responsive to this Subpoena including, but not limited to, any pages showing who reviewed, approved, or rejected a particular document.

4. "Relevant Time Period" means January 1, 2020, through the present date. All responsive documents that were prepared, dated, sent, received, altered, in effect, or which came into existence during this period are to be produced pursuant to this Subpoena.

5. "Or" as well as "and" shall be construed interchangeably in a manner that gives this Subpoena the broadest possible meaning.

6. "Any" shall be construed to include the word "all" and the term "all" shall be construed to include the word "any."

7. "Relate to" means to make a statement about, refer to, discuss, describe, reflect, identify, deal with, consist of, or in any way pertain, in whole or in part to the subject.

8. "Communication" means any transmission or exchange of information, statements, ideas, inquiries, or data between two or more persons orally, in writing, digitally, visually, or electronically regardless of the medium or platform used, including social media interactions, voicemails, and virtual meetings (e.g., Zoom, WebEx, Microsoft Teams). The term includes all drafts, versions, replies, responses, forwards, and attachments associated with or forming part of the communication, as well as any records or logs reflecting the time, date, participants, and content of such communications.

9. "Gender-related care" means any medical, surgical, psychological, or social treatment provided to individuals to alter their physical appearance or social presentation to resemble characteristics typically associated with the opposite biological sex.

10. "Puberty blockers" means any gonadotropin-releasing hormone ("GnRH") agonists or related drugs (*e.g.,* leuprolide, triptorelin) used to delay the onset of puberty.

11. "Hormones" includes testosterone, estrogen, and any other hormonal drugs used in hormonal treatments sometimes known as "gender affirming hormone therapy" ("GAHT") or transgender hormone therapy used to induce cross-sex characteristics.

12. "Minor" means any patient under the age of 18 at the time of consultation, treatment, or prescription.

II. GENERAL INSTRUCTIONS

1. You are required to produce the **originals** of each document and other item that is responsive, in whole or in part, to any request set forth in this Subpoena, together with all copies of any such document that exist.

   a. If a copy is identical to the original, you are not required to produce it, but if you choose not to, your records custodian (the "Custodian," as described below) must maintain a written log identifying the location(s) where each identical copy of the original document was located, including all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers of where the document is located.

   b. If a copy differs from the original by virtue of any addition, deletion, alteration, notation, or inscription on any part of the front or back of the document, the original and copy must each be produced.

2. **No document called for by this subpoena shall be destroyed, modified, redacted, removed, or otherwise made inaccessible.** Documents called for by this Subpoena for which a claim of privilege is made, in compliance with the instruction below, shall be retained and protected.

3. Your Company is to designate someone as the person responsible to produce documents on the Subpoena return date (the "Custodian").

   a. Such Custodian shall have personal, direct, and thorough knowledge of, and responsibility for, the search conducted by the Company for documents responsive to this Subpoena.

   b. The Custodian shall be prepared on the return date to submit to examination concerning the method and completeness of the Company's response, the exact location(s) within the Company's premises at which documents produced in response to the Subpoena were found, and other matters pertaining to the search.

   c. The Custodian shall further be prepared to provide a written log identifying the location(s) in which each produced document was located, indicating all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers, of where the document is located.

4. The Company shall identify the paragraph and subparagraph of Section III of this Attachment to the Subpoena ("Documents to Be Produced") to which each document produced pursuant to this Subpoena is responsive.

5. If the Company has knowledge of any document that would be responsive to this Subpoena, but has been lost, destroyed, or discarded, it shall identify the document to the extent possible, and provide an explanation of the loss, destruction or discarding, including identification of each person authorizing or having knowledge of the loss, destruction, or discarding.

6. The singular form of a word shall be construed to include within its meaning the plural form of the word, and *vice versa*, and the use of any tense of any verb shall be considered to include all other tenses in a manner that gives this Subpoena the broadest reading.

7. All electronically stored information must be collected using a forensically sound process. When the image file is produced, the Company must preserve the integrity of the electronic document's contents, including the original formatting of the document, its metadata and, where applicable, its revision history.

8. If the Company withholds any document on the ground of any claimed privilege, it shall provide a statement with respect to each document setting forth

   a. The name and title of the author (and if different, the preparer and signatory);

   b. The name(s) and title(s) of the individual(s) to whom the document was addressed;

   c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;

   d. The date of the document;

   e. The number of pages;

   f. A brief description of the subject matter;

   g. A statement of the specific basis on which privilege is claimed; and

   h. The paragraph or subparagraph in Section III of this Attachment ("Documents to Be Produced") to which it is responsive.

III. DOCUMENTS TO BE PRODUCED

1. Complete personnel files for each employee, contractor, or affiliate of the Company in the following categories: (a) executives, management employees, or board members with authority to direct any aspect of the Company's affairs; (b) employees, contractors, or affiliates who have authority to prescribe medications or perform medical evaluations; and (c) employees, contractors, or affiliates who are engaged in billing activities.

2. All documents, including billing records, insurance claims, internal protocols, or guidance, concerning the use of ICD (*i.e.*, International Classification of Diseases) diagnosis codes in connection with the treatment of minor patients receiving gender-related care.

3. All documents that show or relate to any use of diagnosis codes for minors other than those specifically identifying transsexualism, gender dysphoria, gender incongruence, or gender identity disorder (*e.g.*, codes for endocrine disorder, unspecified hormonal disorders, medication management, etc.).

4. All documents reflecting communications among Company employees (including physicians, billing staff, and administrators), or between the Company and any third party, relating to whether or how to code or bill for treatment of gender dysphoria by using alternative diagnoses or alternative ICD codes.

5. All communications with public or private health care benefit programs or plans regarding the use of ICD codes for gender-related care, including any inquiries, denials, or appeals related to claims for such care.

6. Any training materials, coding manuals, presentations, or communications relating to billing or coding practices for gender-related care, puberty blockers, or hormone therapy.

7. All documents relating to communications between You and any pharmaceutical manufacturer of puberty blockers or hormones, or any compounding pharmacy providing puberty blockers or hormones, relating to the use of such drugs in gender-related care for minors.

8. All documents relating to communications with pharmaceutical sales representatives, marketing departments, or medical science liaisons regarding the use of puberty blockers or hormones for gender-related care or the treatment of gender dysphoria, including with regard to the safety and efficacy of such drugs for those uses.

9. All documents, including presentations and promotional materials, received from pharmaceutical manufacturers or compounding pharmacies concerning uses of their products in minors for gender-related care or for the treatment of gender dysphoria, including so-called “scientific exchange” materials.

10. All documents relating to contracts, sponsorships, speaking engagements, consulting agreements, grants, or financial or promotional arrangements between You and any manufacturer or compounder of puberty blockers or hormones.

11. Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.

12. For each such patient identified in Subpoena specification 11, *supra*, documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.

13. All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about off-label use (*i.e.,* uses not

approved by the United States Food and Drug Administration) and potential risks.

14. All documents reflecting communications with pharmaceutical manufacturers, compounding pharmacies, or government agencies relating to the safety of puberty blockers or hormones used in the treatment of minor patients.

15. All documents relating to any adverse event, side effect, or medically unfavorable consequence or outcome in a minor patient with regard to gender-related care.

IV. FORM OF PRODUCTION

Documents responsive to this Subpoena should be produced in the format specified in the "Production Specifications," attached as ATTACHMENT B to this Subpoena.

SUBPOENA ATTACHMENT B

Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

Collection of Electronically Stored Information (ESI)

Careful consideration should be given to the methodology, implementation and documentation of ESI collection to ensure that all responsive data and metadata are preserved in the collection process. Consideration should also be given as to whether production media should be encrypted when producing to the government when required by law (i.e. Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), etc. *See* Section 24 below.

1. Specification Modifications

Any modifications or deviations from the Production Specifications may be done only with the express permission of the government and these modifications or deviations should be communicated to the government and approved by the government in written form. Any responsive data or documents that exist in locations or native forms not discussed in these Production Specifications remain responsive and, therefore, arrangements should be made with the government to facilitate their production.

2. Production Format of ESI and Imaged Hard Copy Documents

Responsive ESI shall be produced in its unprocessed form (i.e., in its native format), without altering native electronic file formats and maintains the integrity of all source, custodian, application, embedded and metadata related thereto. The native electronic file formats provided shall be of a type and nature which is functionally useable by all parties. No alteration shall be made to file names or extensions for responsive native electronic files. If a producing party is converting native files to image files for its own purposes, the Government requests a copy of that image file along with production of the native file.

For ESI, a producing party may provide an image file without a native file only if the affected document requires a privilege redaction or other permitted redaction.. Except as outlined below in sections 5 – 21, the redacted document shall be rendered to TIFF image format, and accompanied by an Opticon/Concordance® Image Cross Reference file. Paper documents shall also be imaged pursuant to the requirements below.

All applicable metadata/database (see section 3 below) shall be extracted and provided in Concordance® load file format.

a. **Image File Format:** All imaged documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image.

b. When producing black and white paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi, 1 bit, single-page TIFF files, CCITT

Group IV (2D Compression). When producing in *color,* paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi single-page JPG. Images should be uniquely and sequentially Bates numbered and unless otherwise specified, Bates numbers should be an endorsement on each image.

i. All TIFF file names shall include the unique Bates number burned into the image. (See section 22, below, regarding Bates number instructions.)
ii. All TIFF image files shall be stored with the ".tif" extension.
iii. Images without corresponding extracted text shall be OCR'd using standard COTS products.
    1. An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.
iv. All pages of a document or all pages of a collection of documents that comprise a folder or other logical grouping, including a box, shall be delivered on a single piece of media.
v. No image folder shall contain more than 2,000 images.

c. **Opticon/Concordance® Image Cross Reference file:** Images should be accompanied by an Opticon load file that associates each Bates number with its corresponding single-page TIFF image file. The Cross Reference file should also contain the relative image file path for each Bates numbered page. The Opticon/Concordance® Image Cross Reference file is a page level load file, with each line representing one image.

Below is a sample:

```
REL000000001,,.\IMAGES\001\REL000000001.TIF,Y,,,
REL000000002,,.\IMAGES\001\REL000000002.TIF,,,,
REL000000003,,.\IMAGES\001\REL000000003.TIF,,,,
REL000000004,,.\IMAGES\001\REL000000004.TIF,Y,,,
REL000000005,,.\IMAGES\001\REL000000005.TIF,,,,
```

The fields are, from left to right:

- Field One – (REL000000001) – the Bates Number. This value must be unique for each row in the OPT file. The first page of each document must match the DOCID or BEGDOC# value of the respective document.
- Field Two – (blank) – the volume identifier. This field is not required.
- Field Three – (.\IMAGES\001\REL000000001.TIF) – The relative file path to the image to be loaded.
- Field Four – (Y) – the document marker. A "Y" indicates the start of a unique document.
- Field Five – (blank) – The folder indicator. This field is not required, and typically is not used.

- Field Six – (blank) – The box indicator. This field is not required, and typically is not used.
- Field Seven – (blank) – The page count. This field is not required.

d. **Concordance® Load File**: Images should also be accompanied by a flat, document-level load file to provide the metadata and native files containing delimited text that will populate fields in a searchable, flat database environment. The file encoding must be one of four types: Western European (Windows), Unicode (UTF16), Big-Endian Unicode or UTF8. The file should contain the required fields listed below in section 3.

1. Text delimited load files are defined using the standard Concordance delimiters. For example:

Field Separator	*¶ or Code 020*
Text Qualifier	*þ or Code 254*
Newline	*® or Code 174*
Multi-value	*; or Code 059*
Nested values	*\ or Code 092*

2. This load file should contain the relative file path to the individual multi-page, document level text files.
3. This load file should also contain the relative file path to all provided native files, such as Microsoft Excel or PowerPoint files.
4. There should be one line for every record in a collection.
5. The load file must contain a header listing the metadata/database fields contained within. For example, if the data file consists of a First Page of a Record (BegDoc#), Last Page of a Record (ending Bates / ENDDOC#), DOCID, DOCDate, File Name, and a Title, then the structure may appear as follows:

   þBEGDOCþ¶þENDDOCþ¶þDOCIDþ¶þDOCDATEþ¶þFILENAME þ¶þTITLEþ

d. **The extracted/OCR** text should be provided for each document as a separate single text file. The file name should match the BEGDOC# or DOCID for that specific record and be accompanied by the .txt extension.

e. **Directory and folder structure:** The directory structure for productions should be:

*CaseName***LoadFiles**
*CaseName***Images** < For supporting images (can include subfolders as needed, should not include more than 2,000 files per folder)
*CaseName***Natives** <Native Files location (can include subfolders as needed, should not include more than 2,000 files per folder)
*CaseName***Text** <Extracted Text files location (can include subfolders as needed, should not include more than 2,000 files per folder)

*CaseName***Translated Images** < For supporting images of translated documents (as needed for rendered translated documents; can include subfolders as needed, should not include more than 2,000 files per folder) *CaseName***Translated Text** <Translated Text files location (as needed for translated text; can include subfolders as needed, should not include more than 2,000 files per folder).

3. Required Metadata/Database Fields

A "✓" denotes that the indicated field should be present in the load file produced. "Other ESI" includes data discussed in sections 5 – 21 below, but does not include email, email repositories (section 11), "stand alone" items (section 12), imaged hard copy material (section 9) and production from ESI collected from Smart Phones, Mobile Devices and Other Technology (section 13). Email, email repositories, and "stand alone" materials (section 12) should comply with "Email" column below. Imaged hard copy materials should comply with the "Hard Copy" column. Production from ESI collected from Smart Phones, Mobile Devices and Other Technology should comply with the requirements of section 13. The parties will meet and confer about any field which cannot be populated automatically (i.e. would require manual population of information).

Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
COLLECTION SOURCE	Name of the Company/Organization data was collected from	Text	160	✓	✓	✓
SOURCE ID (BOX #)	Submission/volume/box number	Text	10	✓	✓	✓
CUSTODIAN	Custodian/Source - format: Last, First or ABC Dept.	Text	160	✓	✓	✓
DUPECUSTODIAN	Custodian/Source – all custodians who had the document before de-duplication; format: Last, First or ABC Dept.	Text – semicolon delimited	Unlimited		✓	✓
DUPECUSTODIAN FILE PATH	Listing of all the file locations of the document before de-duplication	Text – semicolon delimited	Unlimited		✓	✓
AUTHOR	Creator of the document	Text	500			✓
BEGDOC#	Start Bates (including prefix) - No spaces	Text	60	✓	✓	✓
ENDDOC#	End Bates (including prefix) - No spaces	Text	60	✓	✓	✓
DOCID	Unique document Bates # or populate with the same value as Start Bates (DOCID = BEGDOC#)	Text	60	✓	✓	✓

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Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
PGCOUNT	Page Count	Number	10	✓	✓	✓
GROUPID	Contains the Group Identifier for the family, in order to group files with their attachments	Text	60		✓	✓
PARENTID	Contains the Document Identifier of an attachment's parent	Text	60		✓	✓
ATTACHIDS	Child document list; Child DOCID or Child Start Bates	Text – semicolon delimited	Unlimited	✓	✓	✓
ATTACHLIST	List of Attachment filenames	Text – semicolon delimited	Unlimited		✓	✓
BEGATTACH	Start Bates number of parent	Text	60	✓	✓	✓
ENDATTACH	End Bates number of last attachment	Text	60	✓	✓	✓
RECORD TYPE	Use the following choices: Image, Loose E-mail, E-mail, E-Doc, Attachment, Hard Copy or Other. If using Other, please specify what type after Other	Text	60	✓	✓	✓
FROM	Sender (i.e.: e-mail address, Last name, First name)	Text	160		✓	✓
TO	Recipient (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		✓	✓
CC	Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		✓	✓
BCC	Blind Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		✓	✓
SUBJECT	Subject line of email	Text	Unlimited		✓	
TITLE	Document Title	Text	Unlimited			✓
CONVINDEX	E-mail system ID used to track replies, forwards, etc.	Text	Unlimited		✓	

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Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
DOCDATE	Last Modified Date for files and Sent date for e-mail, this field inherits the date for attachments from their parent. Do not provide 00/00/0000.	Date	MM/DD/YYYY		✓	✓
TEXT FILEPATH	Relative file path of the text file associated with either the extracted text or the OCR	Text	Unlimited	✓	✓	✓
DATE TIME SENT	Date and time Sent (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	
DATE TIME CRTD	Date Created (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	✓
DATE TIME SVD	Date Saved (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	✓
DATE TIME MOD	Date Last Modified (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	✓
DATE TIME RCVD	Date Received (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	

Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
DATE TIME ACCD	Date Accessed (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	✓
TIME ZONE OFFSET	Time zone of collection locality, relative to Coordinated Universal Time (UTC). E.g., for US Central Standard Time (CST), the value for this field should be -6.0	Decimal	10		✓	
FILE SIZE	Native File Size in KBs	Decimal	10			✓
FILE NAME	File name - name of file as it appeared in its original location	Text	Unlimited			✓
APPLICATION	Application used to create native file (e.g. Excel, Outlook, Word)	Text	160		✓	✓
FILE EXTENSION	Extension for the file (e.g. .doc, .pdf, .wpd)	Text	10		✓	✓
FILEPATH	Data's original source full folder path	Text	Unlimited		✓	✓
NATIVE LINK	Relative file path location to the native file	Text	Unlimited		✓	✓
FOLDER ID	Complete E-mail folder path (e.g. Inbox\Active) or Hard Copy container information (e.g. folder or binder name)	Text	Unlimited	✓	✓	
HASH VALUE	Identifying value of an electronic record that is used for deduplication during processing. MD5 or SHA1 hash algorithms may be used, but must be kept consistent throughout all productions and communicated to Government.	Text	Unlimited		✓	✓
MESSAGEHEADER	E-mail header.	Text	Unlimited		✓	
ATTACHMCOUNT	Number of attachments (any level child document) associated with a ParentID	Text	10		✓	

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Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
FILE TYPE	Description that represents the file type to the Windows Operating System. E.g., Adobe Portable Document Format, Microsoft Word 97 – 2003, or Microsoft Office Word Open XML Format.	Text	160		✓	✓
HAS HIDDEN CONTENT	Identifies whether the document has comments, track changes or other hidden content or data associated with it	Text	Yes/No		✓	✓
MESSAGE TYPE	Exchange Message class or equivalent	Text	60		✓	
EXTENDED PROPERTIES		Text	Unlimited		✓	✓
HAS REDACTIONS	Identifies whether a record has been produced with redactions; should be populated with Y for records with redactions and N for records without redactions.	Text	Yes/No	✓	✓	✓
HAS TRANSLATIONS	Identifies whether a document has been produced with translated text or audio contains a transcript	Text	Yes/No	✓	✓	✓

4. Search, De-Duplication, Near-Duplicate Identification, Technology Assisted Review, E-mail Conversation Threading and Other Culling Procedures

a. De-duplication of exact hash copies shall only be permitted if the producing party can meet all the provisions of this section. If a producing party cannot comply with any requirement of this section, it shall not conduct de-duplication of exact hash copies.
b. De-duplication of exact hash copies shall be performed globally – across all custodians. The custodian of each record shall be populated in the DupeCustodian field.
c. All files found on the National Institute of Standards and Technology (NIST) list, commonly referred to as deNISTing, should be excluded from delivery to the Government. All available metadata from files withheld from delivery due to the deNISTing process will be available upon request.
d. All files should be globally de-duplicated with the following conditions:

i. The "DupeCustodian" metadata field (listing of all custodians who had the document before de-duplication) must be provided with the document production.
ii. The "DupeCustodian File Path" metadata field (listing all the file locations of the document before de-duplication) must be provided with the document production.
iii. All files and metadata for the duplicate documents removed during de-duplication must be preserved and available for production upon request.
iv. No customization of hashing may occur without prior express approval by the Government.
v. De-duplication must be done by document family, not by individual document.
vi. A detailed description of the steps taken to de-duplicate (including the process of obtaining hash values) must be provided to the Government. For every production after the first, a separate Unified Custodian overlay shall be provided. If no overlay is necessary due to the fact that no documents de-duped out in connection with previously produced documents, this shall be expressly stated in the cover letter accompanying the subsequent production(s).

e. The Producing Party shall not use any other procedure to cull, filter, group, separate or de-duplicate, or near-deduplicate, etc. (i.e., reduce the volume of) responsive material before discussing with and obtaining the written approval of the government. All objective coding (e.g., near duplicate ID or e-mail thread ID) shall be discussed and produced to the government as additional metadata fields. The Producing Party will not employ analytic software or technology to search, identify, or review potentially responsive material, including but not limited to, technology assisted review or predictive coding, without first discussing with the government.

5. Hidden Text

All hidden text (e.g. track changes, hidden columns, mark-ups, notes) shall be expanded and rendered in the image file. Except for Adobe PDF files, for any files that cannot be expanded, the native files shall be produced with the image file. If an Adobe PDF's hidden text cannot be expanded and rendered in an image file, it need only be produced in native form if individually requested by a specific document identifier or bates number.

6. Embedded Files and File Links

All non-graphic embedded objects (Word documents, Excel spreadsheets, .wav files, etc.) that are found within a file shall be extracted and produced. For purposes of production, the embedded files shall be treated as attachments to the original file, with the parent/child relationship preserved.

The parties shall meet and confer regarding how to treat file links, including links within e-mails to centralized document repositories (e.g. MS OneDrive and Google Drive).

7. Image-Only Files

All image-only files (non-searchable .pdfs, multi-page TIFFs, Snipping Tool and other screenshots, etc., as well as all other images that contain text) shall be produced with OCR text and metadata/database fields identified in section 3 for "Other ESI."

8. Encrypted Files

Any data (whether individual files or digital containers) that is protected by a password, encryption key, digital rights management, or other encryption scheme, shall be decrypted prior to processing for production.

a. The unencrypted text shall be extracted and provided per section 2.d. The unencrypted files shall be used to render images and provided per sections 2.a and 2.b. The unencrypted native file shall be produced pursuant to sections 10-21.
b. If such protected data is encountered but unable to be processed, each file or container shall be reported as an exception in the accompanying Exception Report (pursuant to section 27) and shall include all available metadata associated with the data, including custodian information.

9. Production of Imaged Hard Copy Records

All imaged hard copy material shall reflect accurate document unitization including all attachments and container information (to be reflected in the PARENTID, ATTACHID, BEGATTACH, ENDATTACH and FOLDERID).

a. Unitization in this context refers to identifying and marking the boundaries of documents within the collection, where a document is defined as the smallest physical fastened unit within a bundle. (e.g., staples, paperclips, rubber bands, folders, or tabs in a binder).
b. The first document in the collection represents the parent document and all other documents will represent the children.
c. All imaged hard copy documents shall be produced as 300 dpi single-page TIFF files, CCITT Group IV (2D Compression). All documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image. Images identified as requiring color shall be produced as color 300 dpi single-page JPEG files.
d. All objective coding (e.g., document date or document author) should be discussed and could be produced to the government as additional metadata/database fields should they be deemed as necessary.

10. Production of Spreadsheets and Presentation Files

All spreadsheet and presentation files (e.g. Excel, PowerPoint) shall be produced in the unprocessed "as kept in the ordinary course of business" state (i.e., in native format), with an associated placeholder image and endorsed with a unique Bates number. *See* section 22 below.

The file produced should maintain the integrity of all source, custodian, application, embedded and related file system metadata.

11. Production of E-mail Repositories

E-mail repositories, also known as e-mail databases (e.g., Outlook PST, Lotus NSF), can contain a variety of items, including: messages, calendars, contacts, tasks, etc. E-mail database systems should not be produced without consultation with and written consent of the government about the format for the production of such databases.

12. Production of Items Originally Generated in E-mail Repositories but Found and Collected Outside of E-mail Repositories, i.e., "Stand-alone" Items

Any parent e-mail or other parent items (e.g., calendar, contacts, tasks, notes, etc.) found and collected outside of e-mail repositories (e.g., items having extensions .msg, .htm, .mht, etc.), shall be produced with the "Loose E-mail" metadata fields outlined in section 3, including but not limited to any attachments, maintaining the family (parent/child) relationship.

13. Production of ESI Collected from Mobile Devices, Messaging Platforms, Workplace Collaboration Tools and Other Technologies

The responding party shall identify, collect, and produce any and all data which is responsive to the requests, collected from mobile devices, messaging platforms, workspace collaboration tools and other technologies. These technologies include, but are not limited to smart phones, cell phones, tablets, PDAs, Blackberry, smart phone data, tablet data, voicemail messaging data, instant messaging, chat messaging, text messaging, Slack, conference call data, video/audio conferencing, workspace collaboration tools (e.g., GoTo Meeting, WebEx, MS Teams, Zoom), and related/similar technologies. However, such data, logs, metadata or other files related thereto, as well as other less common but similar data types, shall be produced after consultation with and written consent of the government about the format for the production of such data.

The expectation of the government is that all familial relationships for all data will be maintained. Similar to email conversations and families, the expectation is that all messages/texts in a conversation will be provided the same conversation index and groupid data (maintaining the familial relationship) allowing the government to read the entire conversation in context. Messages should be produced to align with the formats listed in section 2 and as individual Unicode text files, and attachments should be produced as native files with images and OCR text.

While the parties shall meet and confer on precise metadata formats, as an example, metadata collected from mobile devices shall be provided in formats such as the following:

Field Name	Field Description	Mobile	Mobile Cellebrite Categories								
			Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
TXT-ROWNUMBER	Row number.	✓	#	#	#	#	#	#	#	#	#
TXT-CHATNUMBER	Chat number, identifies chat groups.	✓	Chat #								
TXT-STARTTIME	Start date-time for conversation, calendar item.	✓	Start Time: Date								Start Date: Date
TXT-ENDTIME	End date-time for calendar item.	✓									End Date: Date
TXT-LASTACTIVITYTIME	End date-time for conversation.	✓	Last Activity: Date								
TXT-PARTICIPANTS	Who was involved in the conversation, meeting.	✓	Participants		Party						Attendees
TXT-MESSAGENUMBER	Individual identifier for message.	✓	Instant Message #								
TXT-BODY	Body of the chat, message, item.	✓	Body	Body	Message					Body	
TXT-STATUS	Whether the text was Sent or Read on the device.	✓	Status	Status	Status						Status
TXT-LOCATION	GPS Information.	✓	Location				Location				Location
TXT-TIMESTAMP	Timestamp of item. Equivalent to DateReceived for incoming items or to	✓	Timestamp: Date	Date	Date	Date		Timestamp-Date	Timestamp-Date		

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Field Name	Field Description	Mobile	Mobile Cellebrite Categories								
			Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
	DateSent for outgoing items.										
TXT-READDATE	Date read	✓	Read: Date		Read-Date		Read-Date				
TXT-DELETED	Indicates whether a message was deleted and recovered by Cellebrite.	✓	Deleted - Chat	Deleted		Deleted	Deleted	Deleted	Deleted	Deleted	Deleted
TXT-STARREDMESSAGE	Notes whether the message was flagged.	✓	Starred message				Starred message				
TXT-THREAD-GROUP	Populate with the DOCID of the first text in the chat conversation to allow the entire chat conversation to be grouped as a family. (Sort each device by Chat Number and then by Row Number to assign TXT-THREAD-GROUP identifier). This is NOT the BEGATTACH field or	✓	Chat #								

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Field Name	Field Description	Mobile	Mobile Cellebrite Categories								
			Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
	Relativity Group Identifier.										
TXT-SMSC	Short Message Service Center (handles SMS text messages on behalf of phone service provider)	✓			SMSC						
DIRECTION	Direction of communication ; Outgoing or Incoming.	✓		Direction	Direction	Direction	Direction				
IMPORTANCE		✓		Priority		Priority					Priority
ACCOUNT	Account identifier for device user: email address, phone number, account number.	✓		Name		Account		Name			
DURATION	Duration time of call, voice message, audio, video in HH:MM:SS format, e.g. 00:00:32	✓						Duration	Duration		

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14. Production of Social Media

Prior to any production of responsive data from social media (e.g., Twitter, Facebook, LinkedIn, etc.), the producing party shall first discuss with the government the potential export formats before collecting the information, to ensure it is collected and produced in a way that preserves the original metadata, has a clear chain of custody, and provides as much information as possible regarding the source and history of each individual communication.

Social media platforms offer different functions, forms of content, and capability for downloading accounts. Because of these differences, prior to collection of social media data, the producing party must discuss with the government the available export and production methods and formats that the producing party is considering. Unless the government agrees to an alternative in writing, regardless of the social media platform, productions of social media content must meet the following general requirements: (1) separate (2) searchable (3) static images of (4) each responsive posting on the social media platform, (5) all related content (e.g., comments, likes, share or re-transmittal information, images, videos, linked documents and content), and (6) associated metadata (e.g., user name(s), date, and time of all posts, comments, likes, share or re-transmittals).

These general requirements are in addition to any more specific requirements in a particular request (e.g., geolocation data), and the producing party must ask the government about any perceived conflict between these requirements and another source of specifications or requirements. If available from the social media platform or through social media data processing software, files that facilitate interactive review of the data (i.e., html files) as well as load files in .csv format must be produced with the associated content.

15. Production of Structured Data

Prior to any production of responsive data from a structured database (e.g., Oracle, SAP, SQL, MySQL, QuickBooks, proprietary timekeeping, accounting, sales rep call notes, CRMs, SharePoint, etc.), the producing party shall first identify the database type and version number, discuss providing the database dictionary (in whole or part) and any user manuals, or any other documentation describing the structure and/or content of the database and a list of all reports that can be generated from the database. Upon consultation with and written consent of the government, if a report is provided, the standard format of that report provided should be in comma separated values (.csv) format. The information contained in any such report must be thoroughly explained to the government before production.

16. Production of Photographs with Native File or Digitized ESI

Photographs shall be produced as single-page JPEG files with a resolution equivalent to the original image as they were captured/created. All JPEG files shall have extracted metadata/database fields provided in a Concordance® load file format as outlined in section 3 for "Other ESI."

17. Production of Images from which Text Cannot be OCR Converted

An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.

18. Production of Translated Text with Non-English Language ESI or Documents

To the extent translated text is available to the producing party through machine language translation, such translations shall be provided to the government with the production. The producing party shall provide the original extracted text as well as the translated extracted text in load ready format. The translated text and images of translated documents shall be provided as a separate folder volume to the main production. The parties shall meet and confer regarding any required translated text redactions.

19. Production of Audio File Transcripts

To the extent audio files are produced and transcripts are available to the producing party through machine transcription, such transcripts shall be provided to the government with the production. The producing party shall provide the audio file transcript as a text file in load ready format like any other text file named by the BEGDOC#. The parties shall meet and confer regarding any required audio file redactions.

20. Production of ESI from Non-PC or Non-Windows-based Systems

If responsive ESI is in non-PC or non-Windows-based Systems (e.g., Apple, IBM mainframes, and UNIX machines, Android device, etc.), the ESI shall be produced after discussion with and written consent of the government about the format for the production of such data.

21. Production of Native Files (When Applicable Pursuant to These Specifications)

Production of native files, as called for in these specifications, shall have extracted metadata/database fields provided in a Concordance® load file format as defined in the field specifications for "Other ESI" as outlined in section 3 as well as a placeholder image which indicates a native file is being produced.

ESI shall be produced in a manner which is functionally usable by the government. The following are examples:

a. AutoCAD data, e.g., DWG and DXF files, shall be processed/converted and produced as single-page JPG image files and accompanied by a Concordance® Image formatted load file as described above. The native files shall be placed in a separate folder on the production media and linked by a hyperlink within the text load file.
b. GIS data shall be produced in its native format and be accompanied by a viewer such that the mapping or other data can be reviewed in a manner that does not detract from its ability to be reasonably understood.

c. Audio and video recordings shall be produced in native format and be accompanied by a viewer if such recordings do not play in a generic application (e.g., Windows Media Player).

22. Bates Number Convention

All images should be assigned Bates numbers before production to the government. Each Bates number shall be a standard length, include leading zeros in the number, and be unique for each produced page. The numbers should be endorsed on the actual images at a location that does not obliterate, conceal, or interfere with any information from the source document. Native files should be assigned a single Bates number for the entire file which will represent the native document in the Opticon/ Concordance® Image Cross Reference file. The load file will include a reference to the native file path and utilize the NATIVELINK metadata field). The Bates number shall not exceed 30 characters in length and shall include leading zeros in the numeric portion. The Bates number shall be a unique number given sequentially (i.e. page one of document is PREFIX0000000001, page two of the same document is PREFIX0000000002) to each page (when assigned to an image) or to each document (when assigned to a native file). If the parties agree to a rolling production, the numbering convention shall remain consistent throughout the entire production. There shall be no spaces between the prefix and numeric value. If suffixes are required, please use "dot notation." Below is a sample of dot notation:

	Document #1	*Document #2*
Page #1	PREFIX00000000001	PREFIX00000000002
Page #2	PREFIX00000000001.002	PREFIX00000000002.002
Page #3	PREFIX00000000001.003	PREFIX00000000002.003

23. Media Formats for Storage and Delivery of Production Data

Electronic documents and data shall be delivered on any of the following media:

a. CD-ROMs and/or DVD-R (+/-) formatted to ISO/IEC 13346 and Universal Disk Format 1.02 specifications; Blu-ray.
b. External hard drives (USB 3.0 or higher, formatted to NTFS format specifications) or flash drives
c. Government approved File Transfer Protocol (FTP) technologies.
d. Storage media used to deliver ESI shall be appropriate to the size of the data in the production.
e. Media should be labeled with the case name, production date, Bates range, and producing party.

24. Virus Protection and Security for Delivery of Production Data

Production data shall be free of computer viruses. Any files found to include a virus shall be quarantined by the producing party and noted in a log to be provided to the government. Password protected or encrypted files or media shall be provided with corresponding passwords and specific decryption instructions. All encryption software shall be used with approval by and with the written consent of the government.

25. Privilege Logs

a. The name and title of the author (and if different, the preparer and signatory);
b. The name(s) and title(s) of the individual(s) to whom the document was addressed;
c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
d. The date of the document;
e. The number of pages;
f. A brief description of the subject matter;
g. A statement of the specific basis on which privilege is claimed; and
h. The paragraph or subparagraph of the Subpoena to which it is responsive.

26. Compliance and Adherence to Generally Accepted Technical Standards

Production shall be in conformance with standards and practices established by the National Institute of Standards and Technology ("NIST" at www.nist.gov), U.S. National Archives & Records Administration ("NARA" at www.archives.gov), American Records Management Association ("ARMA International" at www.arma.org), American National Standards Institute ("ANSI" at www.ansi.org), International Organization for Standardization ("ISO" at www.iso.org), and/or other U.S. Government or professional organizations.

27. Read Me Text File

All deliverables shall include a "read me" text file at the root directory containing: total number of records, total number of images/pages or files, mapping of fields to plainly identify field names, types, lengths, and formats. The file shall also indicate the field name to which images will be linked for viewing, date and time format, and confirmation that the number of files in load files matches the number of files produced.

28. Exception Report

An exception report, in .csv format, shall be included, documenting any production anomalies during the collection, processing, and production phases. The report shall provide all available BEGDOC# or DOCID values and metadata listed in section 3, including but not limited to file names and file paths for all affected files.

29. Transmittal Letter to Accompany Deliverables

All deliverables should be accompanied by a transmittal letter including the production date, case name and number, producing party name, and Bates range produced. Technical instructions on how to decrypt media should be included in the transmittal letter but the password should be transmitted separately.

-XXX-

EXHIBIT 9

UNITED STATES OF AMERICA
DEPARTMENT OF JUSTICE

SUBPOENA DUCES TECUM

No. 25-1431-014

To: The Children's Hospital of Philadelphia
3401 Civic Center Boulevard
Philadelphia, Pennsylvania 19104

YOU ARE HEREBY COMMANDED TO APPEAR BEFORE Patrick Runkle, Ross Goldstein, and/or Francisco Unger, officials of the United States Department of Justice, and you are hereby required to bring with you and produce the following:

Please see Attachment A

which are necessary in the performance of the responsibility of the United States Department of Justice to investigate Federal health care offenses as defined in 18 U.S.C. § 24(a).

Please contact Assistant Director Patrick Runkle, Assistant Director Ross Goldstein, or Trial Attorney Francisco Unger at 202-616-0295 if you have any questions regarding this Subpoena Duces Tecum.

PLACE AND TIME FOR APPEARANCE:

U.S. Department of Justice, Consumer Protection Branch, 450 Fifth St., NW, Washington, D.C.
on Wednesday, the 9th day of July, 2025, at ten o'clock a.m.

Failure to comply with the requirements of this subpoena will render you liable to proceedings in the district court of the United States to enforce obedience to the requirements of this subpoena, and to punish default or disobedience.

Issued under authority of Section 248 of the Health Insurance Portability & Accountability Act of 1996, Public Law No. 104-91 (18 U.S.C. § 3486)

IN TESTIMONY WHEREOF

Brett A. Shumate, Assistant Attorney General, the undersigned official of the United States Department of Justice, has set his hand this 11th day June, 2025.

BRETT SHUMATE

Digitally signed by BRETT SHUMATE
Date: 2025.06.11 12:05:50 -04'00'

(signature)

ATTACHMENT A TO SUBPOENA TO:

THE CHILDREN'S HOSPITAL OF PHILADELPHIA
3401 CIVIC CENTER BOULEVARD
PHILADELPHIA, PENNSYLVANIA 19146-2305

I. DEFINITIONS

1. "You," "Your Company," "the Company," and "CHOP" means:

   a. The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation, whose principal place of business is located at 3401 Civic Center Boulevard, Philadelphia, Pennsylvania, without regard to any name under which it has done business;

   b. All of its predecessors, subsidiaries, affiliates, branches, divisions, groups, business units, business segments, operations, units, parent organizations, successors, assigns, plants, and any joint ventures of which they were or are a part, including, without limitation, CHOP's Gender and Sexuality Development Program; and

   c. Each of its present or former officers, directors, employees, attorneys, representatives, and agents acting or purporting to act or appearing to act on behalf of the Company, whether or not acting within the proper scope of his or her actual authority.

2. "Employee" means any person including, but not limited to, any independent contractor or agent, all past and present directors, officers, agents, representatives, attorneys, accountants, advisors, and consultants who acted or purported to act on behalf of the Company or who have performed any service for the Company or under its name, whether on a full-time, part-time, piece-work, commission, volunteer, or other basis, and whether paid or unpaid.

3. "Document" should be afforded the broadest possible meaning and includes every writing or record of whatever type or description, including but not limited to any electronically stored data or paper document, in the possession, custody, or control of the Company. This includes, but is not limited to:

   a. All material that is handwritten, typed, printed, recorded, transcribed, taped, filmed, in graphic form, or in aural form;

b. Drawings, designs, manuals, memoranda, emails, reports, financial reports, notes, diaries, notations of any sort of conversations, working papers, letters, envelopes, telegrams, messages, studies, analyses, books, articles, notebooks, booklets, circulars, bulletins, notices, instructions, pamphlets, pictures, films, videos, voice recordings, maps, work papers, arithmetical computations, calendars (including electronic calendars), date books, task lists, minutes, all communications of any type (e.g., e-mail, voice mail, text messaging, WhatsApp and similar applications), social media content (including posts, messages, comments, and metadata), audio and video files,

c. Electronically stored data on magnetic or optical storage media as an "active" file or files (readily readable by one or more computer applications or forensics software), including metadata;

d. Any electronic files saved as a backup, including metadata;

e. Any deleted but recoverable electronic files, including metadata;

f. Any electronic file fragments (files that have been deleted and partially overwritten with new data), including metadata;

g. Every copy of every document where such copy is not identical to the original because of any addition, deletion, alteration, or notation; and

h. All attachments, enclosures, or other matter affixed to, transmitted with, or incorporated by reference within documents responsive to this Subpoena including, but not limited to, any pages showing who reviewed, approved, or rejected a particular document.

4. "Relevant Time Period" means January 1, 2020, through the present date. All responsive documents that were prepared, dated, sent, received, altered, in effect, or which came into existence during this period are to be produced pursuant to this Subpoena.

5. "Or" as well as "and" shall be construed interchangeably in a manner that gives this Subpoena the broadest possible meaning.

6. "Any" shall be construed to include the word "all" and the term "all" shall be construed to include the word "any."

7. "Relate to" means to make a statement about, refer to, discuss, describe, reflect, identify, deal with, consist of, or in any way pertain, in whole or in part to the subject.

8. "Communication" means any transmission or exchange of information, statements, ideas, inquiries, or data between two or more persons orally, in writing, digitally, visually, or electronically regardless of the medium or platform used, including social media interactions, voicemails, and virtual meetings (e.g., Zoom, WebEx, Microsoft Teams). The term includes all drafts, versions, replies, responses, forwards, and attachments associated with or forming part of the communication, as well as any records or logs reflecting the time, date, participants, and content of such communications.

9. "Gender-related care" means any medical, surgical, psychological, or social treatment provided to individuals to alter their physical appearance or social presentation to resemble characteristics typically associated with the opposite biological sex.

10. "Puberty blockers" means any gonadotropin-releasing hormone ("GnRH") agonists or related drugs (*e.g.*, leuprolide, triptorelin) used to delay the onset of puberty.

11. "Hormones" includes testosterone, estrogen, and any other hormonal drugs used in hormonal treatments sometimes known as "gender affirming hormone therapy" ("GAHT") or transgender hormone therapy used to induce cross-sex characteristics.

12. "Minor" means any patient under the age of 18 at the time of consultation, treatment, or prescription.

II. GENERAL INSTRUCTIONS

1. You are required to produce the **originals** of each document and other item that is responsive, in whole or in part, to any request set forth in this Subpoena, together with all copies of any such document that exist.

   a. If a copy is identical to the original, you are not required to produce it, but if you choose not to, your records custodian (the "Custodian," as described below) must maintain a written log identifying the location(s) where each identical copy of the original document was located, including all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers of where the document is located.

   b. If a copy differs from the original by virtue of any addition, deletion, alteration, notation, or inscription on any part of the front or back of the document, the original and copy must each be produced.

2. **No document called for by this subpoena shall be destroyed, modified, redacted, removed, or otherwise made inaccessible.** Documents called for by this Subpoena for which a claim of privilege is made, in compliance with the instruction below, shall be retained and protected.

3. Your Company is to designate someone as the person responsible to produce documents on the Subpoena return date (the "Custodian").

   a. Such Custodian shall have personal, direct, and thorough knowledge of, and responsibility for, the search conducted by the Company for documents responsive to this Subpoena.

   b. The Custodian shall be prepared on the return date to submit to examination concerning the method and completeness of the Company's response, the exact location(s) within the Company's premises at which documents produced in response to the Subpoena were found, and other matters pertaining to the search.

   c. The Custodian shall further be prepared to provide a written log identifying the location(s) in which each produced document was located, indicating all locations, if more than one. This includes, in the case of information stored in electronic form, a description, including drives, directories, and computers, of where the document is located.

4. The Company shall identify the paragraph and subparagraph of Section III of this Attachment to the Subpoena ("Documents to Be Produced") to which each document produced pursuant to this Subpoena is responsive.

5. If the Company has knowledge of any document that would be responsive to this Subpoena, but has been lost, destroyed, or discarded, it shall identify the document to the extent possible, and provide an explanation of the loss, destruction or discarding, including identification of each person authorizing or having knowledge of the loss, destruction, or discarding.

6. The singular form of a word shall be construed to include within its meaning the plural form of the word, and *vice versa*, and the use of any tense of any verb shall be considered to include all other tenses in a manner that gives this Subpoena the broadest reading.

7. All electronically stored information must be collected using a forensically sound process. When the image file is produced, the Company must preserve the integrity of the electronic document's contents, including the original formatting of the document, its metadata and, where applicable, its revision history.

8. If the Company withholds any document on the ground of any claimed privilege, it shall provide a statement with respect to each document setting forth

a. The name and title of the author (and if different, the preparer and signatory);

b. The name(s) and title(s) of the individual(s) to whom the document was addressed;

c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;

d. The date of the document;

e. The number of pages;

f. A brief description of the subject matter;

g. A statement of the specific basis on which privilege is claimed; and

h. The paragraph or subparagraph in Section III of this Attachment ("Documents to Be Produced") to which it is responsive.

III. DOCUMENTS TO BE PRODUCED

1. Complete personnel files for each employee, contractor, or affiliate of the Company in the following categories: (a) executives, management employees, or board members with authority to direct any aspect of the Company's affairs; (b) employees, contractors, or affiliates who have authority to prescribe medications or perform medical evaluations; and (c) employees, contractors, or affiliates who are engaged in billing activities.

2. All documents, including billing records, insurance claims, internal protocols, or guidance, concerning the use of ICD (*i.e.*, International Classification of Diseases) diagnosis codes in connection with the treatment of minor patients receiving gender-related care.

3. All documents that show or relate to any use of diagnosis codes for minors other than those specifically identifying transsexualism, gender dysphoria, gender incongruence, or gender identity disorder (*e.g.*, codes for endocrine disorder, unspecified hormonal disorders, medication management, etc.).

4. All documents reflecting communications among Company employees (including physicians, billing staff, and administrators), or between the Company and any third party, relating to whether or how to code or bill for treatment of gender dysphoria by using alternative diagnoses or alternative ICD codes.

5. All communications with public or private health care benefit programs or plans regarding the use of ICD codes for gender-related care, including any inquiries, denials, or appeals related to claims for such care.

6. Any training materials, coding manuals, presentations, or communications relating to billing or coding practices for gender-related care, puberty blockers, or hormone therapy.

7. All documents relating to communications between You and any pharmaceutical manufacturer of puberty blockers or hormones, or any compounding pharmacy providing puberty blockers or hormones, relating to the use of such drugs in gender-related care for minors.

8. All documents relating to communications with pharmaceutical sales representatives, marketing departments, or medical science liaisons regarding the use of puberty blockers or hormones for gender-related care or the treatment of gender dysphoria, including with regard to the safety and efficacy of such drugs for those uses.

9. All documents, including presentations and promotional materials, received from pharmaceutical manufacturers or compounding pharmacies concerning uses of their products in minors for gender-related care or for the treatment of gender dysphoria, including so-called "scientific exchange" materials.

10. All documents relating to contracts, sponsorships, speaking engagements, consulting agreements, grants, or financial or promotional arrangements between You and any manufacturer or compounder of puberty blockers or hormones.

11. Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.

12. For each such patient identified in Subpoena specification 11, *supra*, documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.

13. All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in Subpoena specification 11, *supra*, including any disclosures about off-label use (*i.e.*, uses not

approved by the United States Food and Drug Administration) and potential risks.

14. All documents reflecting communications with pharmaceutical manufacturers, compounding pharmacies, or government agencies relating to the safety of puberty blockers or hormones used in the treatment of minor patients.

15. All documents relating to any adverse event, side effect, or medically unfavorable consequence or outcome in a minor patient with regard to gender-related care.

IV. FORM OF PRODUCTION

Documents responsive to this Subpoena should be produced in the format specified in the "Production Specifications," attached as ATTACHMENT B to this Subpoena.

SUBPOENA ATTACHMENT B

Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

Collection of Electronically Stored Information (ESI)

Careful consideration should be given to the methodology, implementation and documentation of ESI collection to ensure that all responsive data and metadata are preserved in the collection process. Consideration should also be given as to whether production media should be encrypted when producing to the government when required by law (i.e. Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), etc. *See* Section 24 below.

1. Specification Modifications

Any modifications or deviations from the Production Specifications may be done only with the express permission of the government and these modifications or deviations should be communicated to the government and approved by the government in written form. Any responsive data or documents that exist in locations or native forms not discussed in these Production Specifications remain responsive and, therefore, arrangements should be made with the government to facilitate their production.

2. Production Format of ESI and Imaged Hard Copy Documents

Responsive ESI shall be produced in its unprocessed form (i.e., in its native format), without altering native electronic file formats and maintains the integrity of all source, custodian, application, embedded and metadata related thereto. The native electronic file formats provided shall be of a type and nature which is functionally useable by all parties. No alteration shall be made to file names or extensions for responsive native electronic files. If a producing party is converting native files to image files for its own purposes, the Government requests a copy of that image file along with production of the native file.

For ESI, a producing party may provide an image file without a native file only if the affected document requires a privilege redaction or other permitted redaction.. Except as outlined below in sections 5 – 21, the redacted document shall be rendered to TIFF image format, and accompanied by an Opticon/Concordance® Image Cross Reference file. Paper documents shall also be imaged pursuant to the requirements below.

All applicable metadata/database (see section 3 below) shall be extracted and provided in Concordance® load file format.

a. **Image File Format:** All imaged documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image.

b. When producing black and white paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi, 1 bit, single-page TIFF files, CCITT

Group IV (2D Compression). When producing in *color*, paper documents scanned to images, or rendered ESI, they shall be produced as 300 dpi single-page JPG. Images should be uniquely and sequentially Bates numbered and unless otherwise specified, Bates numbers should be an endorsement on each image.

i. All TIFF file names shall include the unique Bates number burned into the image. (See section 22, below, regarding Bates number instructions.)
ii. All TIFF image files shall be stored with the ".tif" extension.
iii. Images without corresponding extracted text shall be OCR'd using standard COTS products.
    1. An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.
iv. All pages of a document or all pages of a collection of documents that comprise a folder or other logical grouping, including a box, shall be delivered on a single piece of media.
v. No image folder shall contain more than 2,000 images.

c. **Opticon/Concordance® Image Cross Reference file:** Images should be accompanied by an Opticon load file that associates each Bates number with its corresponding single-page TIFF image file. The Cross Reference file should also contain the relative image file path for each Bates numbered page. The Opticon/Concordance® Image Cross Reference file is a page level load file, with each line representing one image.

Below is a sample:

```
REL000000001,,.\IMAGES\001\REL000000001.TIF,Y,,,
REL000000002,,.\IMAGES\001\REL000000002.TIF,,,,
REL000000003,,.\IMAGES\001\REL000000003.TIF,,,,
REL000000004,,.\IMAGES\001\REL000000004.TIF,Y,,,
REL000000005,,.\IMAGES\001\REL000000005.TIF,,,,
```

The fields are, from left to right:

- Field One – (REL000000001) – the Bates Number. This value must be unique for each row in the OPT file. The first page of each document must match the DOCID or BEGDOC# value of the respective document.
- Field Two – (blank) – the volume identifier. This field is not required.
- Field Three – (.\IMAGES\001\REL000000001.TIF) – The relative file path to the image to be loaded.
- Field Four – (Y) – the document marker. A "Y" indicates the start of a unique document.
- Field Five – (blank) – The folder indicator. This field is not required, and typically is not used.

- Field Six – (blank) – The box indicator. This field is not required, and typically is not used.
- Field Seven – (blank) – The page count. This field is not required.

d. **Concordance® Load File**: Images should also be accompanied by a flat, document-level load file to provide the metadata and native files containing delimited text that will populate fields in a searchable, flat database environment. The file encoding must be one of four types: Western European (Windows), Unicode (UTF16), Big-Endian Unicode or UTF8. The file should contain the required fields listed below in section 3.

1. Text delimited load files are defined using the standard Concordance delimiters. For example:

Field Separator	*¶ or Code 020*
Text Qualifier	*þ or Code 254*
Newline	*® or Code 174*
Multi-value	*; or Code 059*
Nested values	*\ or Code 092*

2. This load file should contain the relative file path to the individual multi-page, document level text files.
3. This load file should also contain the relative file path to all provided native files, such as Microsoft Excel or PowerPoint files.
4. There should be one line for every record in a collection.
5. The load file must contain a header listing the metadata/database fields contained within. For example, if the data file consists of a First Page of a Record (BegDoc#), Last Page of a Record (ending Bates / ENDDOC#), DOCID, DOCDate, File Name, and a Title, then the structure may appear as follows:

þBEGDOCþ¶þENDDOCþ¶þDOCIDþ¶þDOCDATEþ¶þFILENAMEþ¶þTITLEþ

d. **The extracted/OCR** text should be provided for each document as a separate single text file. The file name should match the BEGDOC# or DOCID for that specific record and be accompanied by the .txt extension.

e. **Directory and folder structure:** The directory structure for productions should be:

*CaseName***LoadFiles**
*CaseName***Images** <For supporting images (can include subfolders as needed, should not include more than 2,000 files per folder)
*CaseName***Natives** <Native Files location (can include subfolders as needed, should not include more than 2,000 files per folder)
*CaseName***Text** <Extracted Text files location (can include subfolders as needed, should not include more than 2,000 files per folder)

\CaseName**Translated Images** < For supporting images of translated documents (as needed for rendered translated documents; can include subfolders as needed, should not include more than 2,000 files per folder)
\CaseName**Translated Text** <Translated Text files location (as needed for translated text; can include subfolders as needed, should not include more than 2,000 files per folder).

3. Required Metadata/Database Fields

A "✓" denotes that the indicated field should be present in the load file produced. "Other ESI" includes data discussed in sections 5 – 21 below, but does not include email, email repositories (section 11), "stand alone" items (section 12), imaged hard copy material (section 9) and production from ESI collected from Smart Phones, Mobile Devices and Other Technology (section 13). Email, email repositories, and "stand alone" materials (section 12) should comply with "Email" column below. Imaged hard copy materials should comply with the "Hard Copy" column. Production from ESI collected from Smart Phones, Mobile Devices and Other Technology should comply with the requirements of section 13. The parties will meet and confer about any field which cannot be populated automatically (i.e. would require manual population of information).

Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
COLLECTION SOURCE	Name of the Company/Organization data was collected from	Text	160	✓	✓	✓
SOURCE ID (BOX #)	Submission/volume/box number	Text	10	✓	✓	✓
CUSTODIAN	Custodian/Source - format: Last, First or ABC Dept.	Text	160	✓	✓	✓
DUPECUSTODIAN	Custodian/Source – all custodians who had the document before de-duplication; format: Last, First or ABC Dept.	Text – semicolon delimited	Unlimited		✓	✓
DUPECUSTODIAN FILE PATH	Listing of all the file locations of the document before de-duplication	Text – semicolon delimited	Unlimited		✓	✓
AUTHOR	Creator of the document	Text	500			✓
BEGDOC#	Start Bates (including prefix) - No spaces	Text	60	✓	✓	✓
ENDDOC#	End Bates (including prefix) - No spaces	Text	60	✓	✓	✓
DOCID	Unique document Bates # or populate with the same value as Start Bates (DOCID = BEGDOC#)	Text	60	✓	✓	✓

Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
PGCOUNT	Page Count	Number	10	✓	✓	✓
GROUPID	Contains the Group Identifier for the family, in order to group files with their attachments	Text	60		✓	✓
PARENTID	Contains the Document Identifier of an attachment's parent	Text	60		✓	✓
ATTACHIDS	Child document list; Child DOCID or Child Start Bates	Text – semicolon delimited	Unlimited	✓	✓	✓
ATTACHLIST	List of Attachment filenames	Text – semicolon delimited	Unlimited		✓	✓
BEGATTACH	Start Bates number of parent	Text	60	✓	✓	✓
ENDATTACH	End Bates number of last attachment	Text	60	✓	✓	✓
RECORD TYPE	Use the following choices: Image, Loose E-mail, E-mail, E-Doc, Attachment, Hard Copy or Other. If using Other, please specify what type after Other	Text	60	✓	✓	✓
FROM	Sender (i.e.: e-mail address, Last name, First name)	Text	160		✓	✓
TO	Recipient (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		✓	✓
CC	Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		✓	✓
BCC	Blind Carbon Copy Recipients (i.e.: e-mail address, Last name, First name)	Text – semicolon delimited	Unlimited		✓	✓
SUBJECT	Subject line of email	Text	Unlimited		✓	
TITLE	Document Title	Text	Unlimited			✓
CONVINDEX	E-mail system ID used to track replies, forwards, etc.	Text	Unlimited		✓	

Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
DOCDATE	Last Modified Date for files and Sent date for e-mail, this field inherits the date for attachments from their parent. Do not provide 00/00/0000.	Date	MM/DD/YYYY		✓	✓
TEXT FILEPATH	Relative file path of the text file associated with either the extracted text or the OCR	Text	Unlimited	✓	✓	✓
DATE TIME SENT	Date and time Sent (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	
DATE TIME CRTD	Date Created (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	✓
DATE TIME SVD	Date Saved (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	✓
DATE TIME MOD	Date Last Modified (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	✓
DATE TIME RCVD	Date Received (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YYYY HH:MM:SS		✓	

Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
DATE TIME ACCD	Date Accessed (USE TIME ZONE OF COLLECTION LOCALITY) Numbers must be populated. If date is unknown, leave blank. Do not provide 00/00/0000	Date and Time	MM/DD/YY YY HH:MM:SS		✓	✓
TIME ZONE OFFSET	Time zone of collection locality, relative to Coordinated Universal Time (UTC). E.g., for US Central Standard Time (CST), the value for this field should be -6.0	Decimal	10		✓	
FILE SIZE	Native File Size in KBs	Decimal	10			✓
FILE NAME	File name - name of file as it appeared in its original location	Text	Unlimited			✓
APPLICATION	Application used to create native file (e.g. Excel, Outlook, Word)	Text	160		✓	✓
FILE EXTENSION	Extension for the file (e.g. .doc, .pdf, .wpd)	Text	10		✓	✓
FILEPATH	Data's original source full folder path	Text	Unlimited		✓	✓
NATIVE LINK	Relative file path location to the native file	Text	Unlimited		✓	✓
FOLDER ID	Complete E-mail folder path (e.g. Inbox\Active) or Hard Copy container information (e.g. folder or binder name)	Text	Unlimited	✓	✓	
HASH VALUE	Identifying value of an electronic record that is used for deduplication during processing. MD5 or SHA1 hash algorithms may be used, but must be kept consistent throughout all productions and communicated to Government.	Text	Unlimited		✓	✓
MESSAGEHEADER	E-mail header.	Text	Unlimited		✓	
ATTACHMCOUNT	Number of attachments (any level child document) associated with a ParentID	Text	10		✓	

Field name	Field Description	Field Type	Field Value	Hard Copy	E-mail	Other ESI
FILE TYPE	Description that represents the file type to the Windows Operating System. E.g., Adobe Portable Document Format, Microsoft Word 97 – 2003, or Microsoft Office Word Open XML Format.	Text	160		✓	✓
HAS HIDDEN CONTENT	Identifies whether the document has comments, track changes or other hidden content or data associated with it	Text	Yes/No		✓	✓
MESSAGE TYPE	Exchange Message class or equivalent	Text	60		✓	
EXTENDED PROPERTIES		Text	Unlimited		✓	✓
HAS REDACTIONS	Identifies whether a record has been produced with redactions; should be populated with Y for records with redactions and N for records without redactions.	Text	Yes/No	✓	✓	✓
HAS TRANSLATIONS	Identifies whether a document has been produced with translated text or audio contains a transcript	Text	Yes/No	✓	✓	✓

4. Search, De-Duplication, Near-Duplicate Identification, Technology Assisted Review, E-mail Conversation Threading and Other Culling Procedures

a. De-duplication of exact hash copies shall only be permitted if the producing party can meet all the provisions of this section. If a producing party cannot comply with any requirement of this section, it shall not conduct de-duplication of exact hash copies.

b. De-duplication of exact hash copies shall be performed globally – across all custodians. The custodian of each record shall be populated in the DupeCustodian field.

c. All files found on the National Institute of Standards and Technology (NIST) list, commonly referred to as deNISTing, should be excluded from delivery to the Government. All available metadata from files withheld from delivery due to the deNISTing process will be available upon request.

d. All files should be globally de-duplicated with the following conditions:

i. The "DupeCustodian" metadata field (listing of all custodians who had the document before de-duplication) must be provided with the document production.
ii. The "DupeCustodian File Path" metadata field (listing all the file locations of the document before de-duplication) must be provided with the document production.
iii. All files and metadata for the duplicate documents removed during de-duplication must be preserved and available for production upon request.
iv. No customization of hashing may occur without prior express approval by the Government.
v. De-duplication must be done by document family, not by individual document.
vi. A detailed description of the steps taken to de-duplicate (including the process of obtaining hash values) must be provided to the Government. For every production after the first, a separate Unified Custodian overlay shall be provided. If no overlay is necessary due to the fact that no documents de-duped out in connection with previously produced documents, this shall be expressly stated in the cover letter accompanying the subsequent production(s).

e. The Producing Party shall not use any other procedure to cull, filter, group, separate or de-duplicate, or near-deduplicate, etc. (i.e., reduce the volume of) responsive material before discussing with and obtaining the written approval of the government. All objective coding (e.g., near duplicate ID or e-mail thread ID) shall be discussed and produced to the government as additional metadata fields. The Producing Party will not employ analytic software or technology to search, identify, or review potentially responsive material, including but not limited to, technology assisted review or predictive coding, without first discussing with the government.

5. Hidden Text

All hidden text (e.g. track changes, hidden columns, mark-ups, notes) shall be expanded and rendered in the image file. Except for Adobe PDF files, for any files that cannot be expanded, the native files shall be produced with the image file. If an Adobe PDF's hidden text cannot be expanded and rendered in an image file, it need only be produced in native form if individually requested by a specific document identifier or bates number.

6. Embedded Files and File Links

All non-graphic embedded objects (Word documents, Excel spreadsheets, .wav files, etc.) that are found within a file shall be extracted and produced. For purposes of production, the embedded files shall be treated as attachments to the original file, with the parent/child relationship preserved.

The parties shall meet and confer regarding how to treat file links, including links within e-mails to centralized document repositories (e.g. MS OneDrive and Google Drive).

7. Image-Only Files

All image-only files (non-searchable .pdfs, multi-page TIFFs, Snipping Tool and other screenshots, etc., as well as all other images that contain text) shall be produced with OCR text and metadata/database fields identified in section 3 for "Other ESI."

8. Encrypted Files

Any data (whether individual files or digital containers) that is protected by a password, encryption key, digital rights management, or other encryption scheme, shall be decrypted prior to processing for production.

a. The unencrypted text shall be extracted and provided per section 2.d. The unencrypted files shall be used to render images and provided per sections 2.a and 2.b. The unencrypted native file shall be produced pursuant to sections 10-21.
b. If such protected data is encountered but unable to be processed, each file or container shall be reported as an exception in the accompanying Exception Report (pursuant to section 27) and shall include all available metadata associated with the data, including custodian information.

9. Production of Imaged Hard Copy Records

All imaged hard copy material shall reflect accurate document unitization including all attachments and container information (to be reflected in the PARENTID, ATTACHID, BEGATTACH, ENDATTACH and FOLDERID).

a. Unitization in this context refers to identifying and marking the boundaries of documents within the collection, where a document is defined as the smallest physical fastened unit within a bundle. (e.g., staples, paperclips, rubber bands, folders, or tabs in a binder).
b. The first document in the collection represents the parent document and all other documents will represent the children.
c. All imaged hard copy documents shall be produced as 300 dpi single-page TIFF files, CCITT Group IV (2D Compression). All documents shall be produced in black and white TIFF format unless the image requires color. An image requires color when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image. Images identified as requiring color shall be produced as color 300 dpi single-page JPEG files.
d. All objective coding (e.g., document date or document author) should be discussed and could be produced to the government as additional metadata/database fields should they be deemed as necessary.

10. Production of Spreadsheets and Presentation Files

All spreadsheet and presentation files (e.g. Excel, PowerPoint) shall be produced in the unprocessed "as kept in the ordinary course of business" state (i.e., in native format), with an associated placeholder image and endorsed with a unique Bates number. *See* section 22 below.

The file produced should maintain the integrity of all source, custodian, application, embedded and related file system metadata.

11. Production of E-mail Repositories

E-mail repositories, also known as e-mail databases (e.g., Outlook PST, Lotus NSF), can contain a variety of items, including: messages, calendars, contacts, tasks, etc. E-mail database systems should not be produced without consultation with and written consent of the government about the format for the production of such databases.

12. Production of Items Originally Generated in E-mail Repositories but Found and Collected Outside of E-mail Repositories, i.e., "Stand-alone" Items

Any parent e-mail or other parent items (e.g., calendar, contacts, tasks, notes, etc.) found and collected outside of e-mail repositories (e.g., items having extensions .msg, .htm, .mht, etc.), shall be produced with the "Loose E-mail" metadata fields outlined in section 3, including but not limited to any attachments, maintaining the family (parent/child) relationship.

13. Production of ESI Collected from Mobile Devices, Messaging Platforms, Workplace Collaboration Tools and Other Technologies

The responding party shall identify, collect, and produce any and all data which is responsive to the requests, collected from mobile devices, messaging platforms, workspace collaboration tools and other technologies. These technologies include, but are not limited to smart phones, cell phones, tablets, PDAs, Blackberry, smart phone data, tablet data, voicemail messaging data, instant messaging, chat messaging, text messaging, Slack, conference call data, video/audio conferencing, workspace collaboration tools (e.g., GoTo Meeting, WebEx, MS Teams, Zoom), and related/similar technologies. However, such data, logs, metadata or other files related thereto, as well as other less common but similar data types, shall be produced after consultation with and written consent of the government about the format for the production of such data.

The expectation of the government is that all familial relationships for all data will be maintained. Similar to email conversations and families, the expectation is that all messages/texts in a conversation will be provided the same conversation index and groupid data (maintaining the familial relationship) allowing the government to read the entire conversation in context. Messages should be produced to align with the formats listed in section 2 and as individual Unicode text files, and attachments should be produced as native files with images and OCR text.

While the parties shall meet and confer on precise metadata formats, as an example, metadata collected from mobile devices shall be provided in formats such as the following:

Field Name	Field Description	Mobile	Mobile Cellebrite Categories								
			Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
TXT-ROWNUMBER	Row number.	✓	#	#	#	#	#	#	#	#	#
TXT-CHATNUMBER	Chat number, identifies chat groups.	✓	Chat #								
TXT-STARTTIME	Start date-time for conversation, calendar item.	✓	Start Time: Date								Start Date: Date
TXT-ENDTIME	End date-time for calendar item.	✓									End Date: Date
TXT-LASTACTIVITYTIME	End date-time for conversation.	✓	Last Activity: Date								
TXT-PARTICIPANTS	Who was involved in the conversation, meeting.	✓	Participants		Party						Attendees
TXT-MESSAGENUMBER	Individual identifier for message.	✓	Instant Message #								
TXT-BODY	Body of the chat, message, item.	✓	Body	Body	Message					Body	
TXT-STATUS	Whether the text was Sent or Read on the device.	✓	Status	Status	Status						Status
TXT-LOCATION	GPS Information.	✓	Location				Location				Location
TXT-TIMESTAMP	Timestamp of item. Equivalent to DateReceived for incoming items or to	✓	Timestamp: Date	Date	Date	Date		Timestamp-Date	Timestamp-Date		

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Field Name	Field Description	Mobile	Mobile Cellebrite Categories								
			Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
	DateSent for outgoing items.										
TXT-READDATE	Date read	✓	Read: Date		Read-Date		Read-Date				
TXT-DELETED	Indicates whether a message was deleted and recovered by Cellebrite.	✓	Deleted - Chat	Deleted		Deleted	Deleted	Deleted	Deleted	Deleted	Deleted
TXT-STARREDMESSAGE	Notes whether the message was flagged.	✓	Starred message				Starred message				
TXT-THREAD-GROUP	Populate with the DOCID of the first text in the chat conversation to allow the entire chat conversation to be grouped as a family. (Sort each device by Chat Number and then by Row Number to assign TXT-THREAD-GROUP identifier). This is NOT the BEGATTACH field or	✓	Chat #								

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Field Name	Field Description	Mobile	Mobile Cellebrite Categories								
			Chats	MMS	SMS	Email	Instant Message	Voicemail	Recordings	Notes	Calendar
	Relativity Group Identifier.										
TXT-SMSC	Short Message Service Center (handles SMS text messages on behalf of phone service provider)	✓			SMSC						
DIRECTION	Direction of communication ; Outgoing or Incoming.	✓		Direction	Direction	Direction	Direction				
IMPORTANCE		✓		Priority		Priority					Priority
ACCOUNT	Account identifier for device user: email address, phone number, account number.	✓		Name		Account		Name			
DURATION	Duration time of call, voice message, audio, video in HH:MM:SS format, e.g. 00:00:32	✓						Duration	Duration		

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14. Production of Social Media

Prior to any production of responsive data from social media (e.g., Twitter, Facebook, LinkedIn, etc.), the producing party shall first discuss with the government the potential export formats before collecting the information, to ensure it is collected and produced in a way that preserves the original metadata, has a clear chain of custody, and provides as much information as possible regarding the source and history of each individual communication.

Social media platforms offer different functions, forms of content, and capability for downloading accounts. Because of these differences, prior to collection of social media data, the producing party must discuss with the government the available export and production methods and formats that the producing party is considering. Unless the government agrees to an alternative in writing, regardless of the social media platform, productions of social media content must meet the following general requirements: (1) separate (2) searchable (3) static images of (4) each responsive posting on the social media platform, (5) all related content (e.g., comments, likes, share or re-transmittal information, images, videos, linked documents and content), and (6) associated metadata (e.g., user name(s), date, and time of all posts, comments, likes, share or re-transmittals).

These general requirements are in addition to any more specific requirements in a particular request (e.g., geolocation data), and the producing party must ask the government about any perceived conflict between these requirements and another source of specifications or requirements. If available from the social media platform or through social media data processing software, files that facilitate interactive review of the data (i.e., html files) as well as load files in .csv format must be produced with the associated content.

15. Production of Structured Data

Prior to any production of responsive data from a structured database (e.g., Oracle, SAP, SQL, MySQL, QuickBooks, proprietary timekeeping, accounting, sales rep call notes, CRMs, SharePoint, etc.), the producing party shall first identify the database type and version number, discuss providing the database dictionary (in whole or part) and any user manuals, or any other documentation describing the structure and/or content of the database and a list of all reports that can be generated from the database. Upon consultation with and written consent of the government, if a report is provided, the standard format of that report provided should be in comma separated values (.csv) format. The information contained in any such report must be thoroughly explained to the government before production.

16. Production of Photographs with Native File or Digitized ESI

Photographs shall be produced as single-page JPEG files with a resolution equivalent to the original image as they were captured/created. All JPEG files shall have extracted metadata/database fields provided in a Concordance® load file format as outlined in section 3 for "Other ESI."

17. Production of Images from which Text Cannot be OCR Converted

An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the DOCID or Bates number(s) corresponding to each such image.

18. Production of Translated Text with Non-English Language ESI or Documents

To the extent translated text is available to the producing party through machine language translation, such translations shall be provided to the government with the production. The producing party shall provide the original extracted text as well as the translated extracted text in load ready format. The translated text and images of translated documents shall be provided as a separate folder volume to the main production. The parties shall meet and confer regarding any required translated text redactions.

19. Production of Audio File Transcripts

To the extent audio files are produced and transcripts are available to the producing party through machine transcription, such transcripts shall be provided to the government with the production. The producing party shall provide the audio file transcript as a text file in load ready format like any other text file named by the BEGDOC#. The parties shall meet and confer regarding any required audio file redactions.

20. Production of ESI from Non-PC or Non-Windows-based Systems

If responsive ESI is in non-PC or non-Windows-based Systems (e.g., Apple, IBM mainframes, and UNIX machines, Android device, etc.), the ESI shall be produced after discussion with and written consent of the government about the format for the production of such data.

21. Production of Native Files (When Applicable Pursuant to These Specifications)

Production of native files, as called for in these specifications, shall have extracted metadata/database fields provided in a Concordance® load file format as defined in the field specifications for "Other ESI" as outlined in section 3 as well as a placeholder image which indicates a native file is being produced.

ESI shall be produced in a manner which is functionally usable by the government. The following are examples:

a. AutoCAD data, e.g., DWG and DXF files, shall be processed/converted and produced as single-page JPG image files and accompanied by a Concordance® Image formatted load file as described above. The native files shall be placed in a separate folder on the production media and linked by a hyperlink within the text load file.
b. GIS data shall be produced in its native format and be accompanied by a viewer such that the mapping or other data can be reviewed in a manner that does not detract from its ability to be reasonably understood.

c. Audio and video recordings shall be produced in native format and be accompanied by a viewer if such recordings do not play in a generic application (e.g., Windows Media Player).

22. Bates Number Convention

All images should be assigned Bates numbers before production to the government. Each Bates number shall be a standard length, include leading zeros in the number, and be unique for each produced page. The numbers should be endorsed on the actual images at a location that does not obliterate, conceal, or interfere with any information from the source document. Native files should be assigned a single Bates number for the entire file which will represent the native document in the Opticon/ Concordance® Image Cross Reference file. The load file will include a reference to the native file path and utilize the NATIVELINK metadata field). The Bates number shall not exceed 30 characters in length and shall include leading zeros in the numeric portion. The Bates number shall be a unique number given sequentially (i.e. page one of document is PREFIX0000000001, page two of the same document is PREFIX0000000002) to each page (when assigned to an image) or to each document (when assigned to a native file). If the parties agree to a rolling production, the numbering convention shall remain consistent throughout the entire production. There shall be no spaces between the prefix and numeric value. If suffixes are required, please use "dot notation." Below is a sample of dot notation:

	Document #1	*Document #2*
Page #1	PREFIX00000000001	PREFIX00000000002
Page #2	PREFIX00000000001.002	PREFIX00000000002.002
Page #3	PREFIX00000000001.003	PREFIX00000000002.003

23. Media Formats for Storage and Delivery of Production Data

Electronic documents and data shall be delivered on any of the following media:

a. CD-ROMs and/or DVD-R (+/-) formatted to ISO/IEC 13346 and Universal Disk Format 1.02 specifications; Blu-ray.
b. External hard drives (USB 3.0 or higher, formatted to NTFS format specifications) or flash drives
c. Government approved File Transfer Protocol (FTP) technologies.
d. Storage media used to deliver ESI shall be appropriate to the size of the data in the production.
e. Media should be labeled with the case name, production date, Bates range, and producing party.

24. Virus Protection and Security for Delivery of Production Data

Production data shall be free of computer viruses. Any files found to include a virus shall be quarantined by the producing party and noted in a log to be provided to the government. Password protected or encrypted files or media shall be provided with corresponding passwords and specific decryption instructions. All encryption software shall be used with approval by and with the written consent of the government.

25. Privilege Logs

a. The name and title of the author (and if different, the preparer and signatory);
b. The name(s) and title(s) of the individual(s) to whom the document was addressed;
c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
d. The date of the document;
e. The number of pages;
f. A brief description of the subject matter;
g. A statement of the specific basis on which privilege is claimed; and
h. The paragraph or subparagraph of the Subpoena to which it is responsive.

26. Compliance and Adherence to Generally Accepted Technical Standards

Production shall be in conformance with standards and practices established by the National Institute of Standards and Technology ("NIST" at www.nist.gov), U.S. National Archives & Records Administration ("NARA" at www.archives.gov), American Records Management Association ("ARMA International" at www.arma.org), American National Standards Institute ("ANSI" at www.ansi.org), International Organization for Standardization ("ISO" at www.iso.org), and/or other U.S. Government or professional organizations.

27. Read Me Text File

All deliverables shall include a "read me" text file at the root directory containing: total number of records, total number of images/pages or files, mapping of fields to plainly identify field names, types, lengths, and formats. The file shall also indicate the field name to which images will be linked for viewing, date and time format, and confirmation that the number of files in load files matches the number of files produced.

28. Exception Report

An exception report, in .csv format, shall be included, documenting any production anomalies during the collection, processing, and production phases. The report shall provide all available BEGDOC# or DOCID values and metadata listed in section 3, including but not limited to file names and file paths for all affected files.

29. Transmittal Letter to Accompany Deliverables

All deliverables should be accompanied by a transmittal letter including the production date, case name and number, producing party name, and Bates range produced. Technical instructions on how to decrypt media should be included in the transmittal letter but the password should be transmitted separately.

-XXX-

EXHIBIT 10

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE ADMINISTRATIVE SUBPOENA NO. 25-1431-019	C.A. No. 1:25-MC-91324-MJJ

[PROPOSED] AMICUS BRIEF OF MASSACHUSETTS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, ILLINOIS, MAINE, MARYLAND, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, OREGON, RHODE ISLAND, VERMONT, WASHINGTON, AND WISCONSIN AS *AMICI CURIAE* IN OPPOSITION TO GOVERNMENT'S MOTION TO ALTER OR AMEND

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INTRODUCTION AND STATEMENT OF INTERESTS

The Commonwealth of Massachusetts and California, Colorado, Connecticut, Delaware, the District of Columbia, Illinois, Maine, Maryland, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, and Wisconsin ("Amici States") submit this brief in opposition to the Government's Motion to Alter or Amend pursuant to Fed. R. Civ. P. 59(e) and 60(b). Amici States are home to hospitals, like Boston Children's Hospital ("BCH"), that provide essential and life-saving care to thousands of people every year, including gender-affirming care to individuals under the age of 19. These hospitals are at the forefront of biomedical and technological research, and they fuel the economies of Amici States, including by creating jobs, spurring innovation, improving residents' health, and training the future workforce.

The subpoena served by the Department of Justice ("DOJ") was properly quashed because it is pretextual and seeks to intimidate medical providers from offering critical, medically necessary health care to transgender youth, one of the most vulnerable populations in Amici States. Indeed, the subpoena places medical providers and hospital administrators in the crosshairs of civil and criminal enforcement mechanisms, including prosecutions, merely for providing this care. DOJ's baseless attempt to sweep the routine prescription and administration of medications for off-label use into federal criminal prohibitions in pursuit of its stated goal of "ending" gender-affirming care will cause profound disruptions across the entire medical field.

Amici have strong interests in regulating the practice of medicine in their jurisdictions, including by licensing doctors and other medical professionals; implementing standards of care for a wide variety of medical procedures and treatments; and enforcing those standards and other related regulations. In this realm, many Amici States have enacted laws safeguarding access to

gender-affirming health care services and protecting people who lawfully provide or help others access such care. In many Amici States' experience, these laws are necessary to uphold the rights and dignity of our transgender residents and the health and well-being of our communities.

In its motion, DOJ attempts to justify its invasion of this traditional sphere of state regulation by pointing to the federal Food, Drug, and Cosmetic Act ("FDCA"), but its interpretation of that statute is exceedingly broad, disruptive, and untethered to precedent and practice. Indeed, DOJ's interpretation appears to conflict with decades of settled precedent concerning medical providers' *use* of approved medications for off-label purposes—something that the law has never been understood to reach. Moreover, DOJ's suggestion here—that the FDCA's prohibitions concerning the distribution and labeling of off-label drugs should be applied to the provision of routine medical care and to standard communications between doctors and patients—would impose potential criminal liability to those who administer a sweeping array of health care. DOJ offers no limiting principle to its argument; if DOJ's interpretation of the FDCA were accepted, entire fields of medicine could see their practitioners at risk of criminal conviction merely for offering evidence-based treatments in accordance with the prevailing standards of care. If BCH were forced to comply with this subpoena and DOJ were to prevail in its interpretation of the FDCA, it would threaten the health and welfare of the people of Massachusetts and other Amici States, impede core economic activities of Amici States, and encroach on Amici States' traditional role as the regulators of medicine.

For the reasons advanced below and by BCH, the Court should deny DOJ's motion to alter or amend the judgment.

ARGUMENT

I. DOJ Seeks to Interfere with Amici States' Authority to Regulate the Practice of Medicine.

As sovereigns of their respective territories, States reserve the power to provide for the health, welfare, safety, and security of the people. *See Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985); *see also Linder v. United States*, 268 U.S. 5, 18 (1925); *Bergman v. Parker*, 348 U.S. 26, 32 (1954); *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985). Accordingly, and to avoid encroaching on the practice of medicine, federal agencies, including the Food and Drug Administration (FDA), have historically recognized that the FDCA does not reach the *use* of off-label medications. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *see also, e.g.*, Notice of Proposed Rulemaking, *Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed. Reg. 16503, 16503 (Aug. 15, 1972). Recent actions by DOJ, including the subpoena at issue in this case, seek to upend these fundamental principles.

The Tenth Amendment reserves for the States all rights and powers "not delegated to the United States" federal government.[1] Commonly referred to as "traditional state police powers," the rights and powers of the States include the "power to protect the health and safety of their citizens."[2] Since at least 1889, the authority to regulate the practice of medicine has been among these powers.[3] Though Congress may legislate to regulate interstate activities, the Executive

[1] U.S. Const. amend. X.

[2] U.S. Const. amend. X; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *see also Slaughterhouse Cases*, 83 U.S. 36, 62 (1873) (describing the police power as extending "to the protection of the lives, limbs, health, comfort, and quiet of all persons…within the State").

[3] *Dent v. West Virginia*, 129 U.S. 114, 122 (1889) (states have discretion to set medical licensing requirements as they have done since "time immemorial").

may not adopt novel interpretations of statutes in order to disrupt a State's medical regulatory framework by inventing novel forms of criminal activity. *See Gonzales v. Oregon*, 546 U.S. 240, 269-70 (holding that Controlled Substances Act did not prohibit Oregon doctors from prescribing medication for the purpose of medical aid in dying, where such care had been enacted through ballot measure). Courts have upheld a broad set of "state medical practice laws against constitutional challenges, making clear that states are generally authorized to legislate in the medical practice area."[4]

States have exercised their power to regulate medicine in various ways. Perhaps most significantly, states regulate the practice of medicine by defining the scope and contours of medical practice and requiring medical licenses for practitioners.[5] Since 1895, all states have boards that oversee the licensing of medical professionals.[6] Fundamental and consistent requirements for obtaining a medical license across states include graduation from an accredited medical school, completing one or more years of residency or fellowship, and passing a licensing examination.[7] Additional requirements may include interviews, a documented lack of criminal

[4] Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 448 (2015); *see also Hillsborough Cnty.*, 471 U.S. at 719 (stating "the regulation of health and safety matters is primarily, and historically, a matter of local concern"); *Watson v. Maryland*, 218 U.S. 173, 176 (1910) (the police power of the states extends to the regulation of certain trades and callings, particularly those which closely concern the public health" and discussing licensing of medical practitioners); *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007) ("Under our precedents it is clear the State has a significant role to play in regulating the medical profession."); *Barsky v. Bd. of Regents*, 347 U.S. 442, 451 (1954) (indicating that the state has "legitimate concern for maintaining high standards of professional conduct" in the practice of medicine); *Buckman*, 531 U.S. at 348 (identifying "historic primacy of state regulation of matters of health and safety").

[5] Zettler, *supra* note 4, at 449-50 (citing ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE 19 (2007) (stating that the "cornerstone" of medical practice regulation is states' licensing schemes).

[6] ROBERT C. DERBYSHIRE, MEDICAL LICENSING AND DISCIPLINE IN THE UNITED STATES 8 (1969); Zettler, *supra* note 4, at 450; ; *see also* Federation of State Medical Boards, *Contact a State Medical Board (n.d.)*, https://www.fsmb.org/contact-a-state-medical-board.

[7] Zettler, *supra* note 4, at 450 (citing Nadia N. Sawicki, *Character, Competence and the Principles of Medical Discipline*, 13 HEALTH CARE L. & POL'Y 285, 290 (2010).

history, and medical malpractice insurance coverage.[8] States, through their legislatures and regulatory boards, also regulate medical practice by disciplining licensees who act illegally or unethically and by "enact[ing] laws and regulations that directly circumscribe how licensed practitioners conduct medical practice," such as reporting, disclosure, and timeframe rules.[9]

States have also exercised their police powers to protect vulnerable groups against discrimination and ensure equal access to critical health care. Consistent with state policy judgments about protecting minority populations and prohibiting discrimination, many Amici have enacted civil rights protections for transgender people in education, employment, health care, housing, public accommodations, and other parts of public life.[10] They have also taken steps to safeguard access to gender-affirming care for transgender people, exercising their sovereign judgment that such safeguards promote public health and wellbeing. For instance, Massachusetts and many other Amici States expressly recognize a legal right to gender-affirming care and have enacted laws intended to protect people in their States who access, provide, or assist with the provision of that care from civil or criminal penalties by out-of-state jurisdictions that outlaw it.[11] Some State licensing boards—like the Boards of Registration in Medicine and

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[8] Zettler, *supra* note 4, at 450.

[9] *Id.* at 450-52.

[10] *See, e.g.*, Mass. Gen. Laws ch. 151B, § 4; Mass. Gen. Laws ch. 272, §§ 92A, 98; Cal. Civ. Code §§ 51(b), 51(e)(5); Cal. Gov't Code §§ 12940(a), 12955; Md. Code Ann., Educ. § 26-704; Conn. Gen. Stat. §§ 10-15c, 46a-58 *et seq.*; Del. Code tit. 6, ch. 45 & 46; Del. Code tit. 19, ch. 7; D.C. Code § 2-1401.01 *et seq.*; Haw. Rev. Stat. §§ 368-1, 378-2, 489-3, 515-3; 775 Ill. Comp. Stat. 5/1-102(A), 5/1-103(O-1), 5/1-103(Q); Me. Rev. Stat. tit. 5, § 4551 *et seq.*; Md. Code Ann., State Gov't §§ 20-606, 20-705; Minn. Stat. §§ 363A.03, subd. 50; 363A.01 *et seq.*; Nev. Rev. Stat. §§ 118.100, 284.150(3), 439.994, 449.101(1), 613.330; N.J. Stat. Ann. §§ 10:5-1 *et seq.*, 17:48-6oo, 18A:36-41; N.Y. Exec. Law §§ 296, 296-a, 296-b; N.Y. Civil Rights Law § 40-c; N.Y. Comp. Codes R. & Regs. tit. 9, § 466.13; Or. Rev. Stat. §§ 659A.006, 659A.030, 659A.403, 659A.421; R.I. Gen. Laws §§ 11-24-2, 23-17-19, 28-5-5, 28-5.1-12, 28-6-18, 34-37-2, 34-37-4, 34-37-4.3, 34-37-5.2, 34-37-5.3, 34-37-5.4; Vt. Stat. Ann. tit. 9, §§ 4502, 4503; Vt. Stat. Ann. tit. 21, § 495; Wash. Rev. Code §§ 49.60.030(1), 49.60.040(2), 49.60.040(29), 49.60.215.

[11] *See, e.g.*, Mass. Gen. Laws ch. 12, § 11I½(b)-(d); Mass. Gen. Laws ch. 147, § 63; Mass. Gen. Laws ch. 276, § 13; Cal. Civ. Code § 56.109; Colo. Rev. Stat. §§ 10-16-121(1)(f), 12-30-121, 13-21-133, 16-3-102, 16-3-301; Conn. Gen. Stat. §§ 19a-17e, 52-146w, 52-146x, 52-571m, 52-571n, 54-155b; 735 Ill. Comp. Stat. 40/28-5, *et seq.*; Me. Rev. Stat. tit. 14, § 9001, *et seq.*; Me. Rev. Stat. tit. 22, §§ 1508; Md. Code Ann., State Pers. & Pens. § 2-312; 2023

in Nursing in Massachusetts—also instruct licensees that they shall not withhold or deny care based on a patient's gender identity.[12] Many Amici also cover gender-affirming care through their State Medicaid programs,[13] and they prohibit State-regulated health insurance plans from withholding coverage from individuals based on their gender identity or gender dysphoria, thereby ensuring that transgender residents enjoy the same coverage for medically necessary treatment as residents who are not transgender.[14]

Similarly, many Amici States have enacted laws that exclude the provision of gender-affirming care from the definition of "professional misconduct" and that shield medical providers from facing professional discipline based solely on an out-of-state conviction or adverse license action resulting from the provision of gender-affirming care.[15] Other Amici States, meanwhile, mandate training for health care professionals to ensure that patients who identify as transgender,

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Minn. Laws ch. 29; Minn. Stat. § 260.925; N.Y. Exec. Law § 837-x; N.Y. Comp. Codes R. & Regs. tit. 10, § 405.7(c)(2); Or. Rev. Stat. §§ 15.430, 24.500, 414.769, 435.210, 435.240; Vt. Stat. Ann. tit. 12, § 7301 *et seq.*; Wash. Rev. Code § 7.115 *et seq.*; N.J.A.C. Executive Order No. 326 (2023); *see also* UCLA Sch. of Law Williams Inst., *Shield Laws for Reproductive and Gender-Affirming Health Care: A State Law Guide*, https://williamsinstitute.law.ucla.edu/publications/shield-laws-fact-sheets.

[12] *See* 244 Code Mass. Regs. § 9.03(13); Mass. Bd. of Reg. in Medicine Policy 16-01: Policy on Gender Identity and the Physician Profile Program, *available at* https://www.mass.gov/lists/physician-regulations-policies-and-guidelines.

[13] *See, e.g.,* Gender-Affirming Care Covered by MassHealth, https://www.mass.gov/info-details/gender-affirming-care-covered-by-masshealth; Md. Code Ann., Health-Gen. § 15-151; 89 Ill. Adm. Code §§ 140.413(a)(16), 140.440(h); Minn. Stat. § 256B.0625, subd. 3a; Nev. Medicaid Servs. Manual § 608, *available at* https://bit.ly/NVMedicaid; R.I. Gender Dysphoria/Gender Nonconformity Coverage Guidelines (Oct. 28, 2015), *available at* https://bit.ly/RI-Guidelines.

[14] *See, e.g.*, Mass. Gen. Laws ch. 272, §§92A, 98; Cal. Code Regs. tit. 10 §2561.2, subd. (a) (2012); 3 Code Colo. Regs. §702-4, Reg. 4-2-42, §5(A)(1)(o); Del. Code tit. 18, §2304; 215 Ill. Comp. Stat. 5/356z.60(b); 50 Ill. Adm. Code §2603.35; Me. Rev. Stat. tit. 22, §3174-MMM; Md. Code Ann., Ins. §15-1A-22; Minn. Stat. §62Q.585; N.J. Stat. Ann. §17:48-6oo; N.Y. Comp. Codes R. & Regs. tit. 11, §52.75; Or. Admin. R. 836-053-0441; Vt. Stat. Ann. tit. 8, §§4724, §4088m; Mass. Div. of Ins. Bulls. 2021-11, 2014-03, *available at* https://www.mass.gov/lists/doi-bulletins; R.I. Health Ins. Bull. 2015-03, *available at* https://bit.ly/RI-2015-03.

[15] *See, e.g.,* Mass. Gen. Laws ch. 112, §§ 5F½, 77, 128; Cal. Bus. & Prof. Code §§ 850.1, 852, 2253, 2761.1; Conn. Gen. Stat. §§ 19a-17e, 20-579a, 52-571m; Colo. Rev. Stat. § 12-30-121; Md. Code Ann., Health Occ. § 1-227; N.Y. Educ. Law § 6531-b; Or. Rev. Stat. §§ 675.070, 675.540, 675.745, 677.190, 678.138, 685.110, 689.405; 225 Ill. Comp. Stat. 60/22(C). Relatedly, some Amicus States bar medical malpractice insurers from discriminating against medical professionals solely because they provide gender-affirming care. *See, e.g.*, Colo. Rev. Stat. § 10-4-109.6(1); Or. Rev. Stat. § 676.313.

gender diverse, and intersex receive trans-inclusive care.[16]

Taken together, the above laws and policies reflect many Amici States' commitment to preserving the integrity of the medical profession, protecting the equality of all people, and ensuring that people with gender dysphoria are not denied medically necessary health care. In the experience of many Amici States, these laws and policies are essential to address long-standing inequities in the health care system. The laws and policies discussed above adhere to medical standards of care and respect the doctor-patient relationship, thereby preserving the integrity and ethics of the medical profession. More importantly, these laws result in better health outcomes for transgender adolescents, safeguarding their physical, emotional, and financial wellbeing.

Despite no federal law prohibiting such care, the clear purpose of DOJ's subpoena to BCH is to end gender-affirming care for transgender adolescents. Br. 11. DOJ's sweeping requests for sensitive information—including records of all patients who have received a particular type of medical care—appear to represent a radical departure from its prior practice and makes express the "policy goal" of the Executive Branch to harm a politically disfavored minority. *See id.*; *see also* ECF No. 33 at 14 ("It is abundantly clear that the true purpose of issuing the subpoena is to interfere with the Commonwealth of Massachusetts' right to protect [gender-affirming care] within its borders, to harass and intimidate BCH to stop providing such care, and to dissuade patients from seeking such care."). The subpoena has nothing at all to do with promoting the rule of law. Rather, this extraordinary overreach is an attempt to subvert the policy and judgment of the states as the traditional regulators of the practice of medicine. The broadside attack by DOJ on gender-affirming care undermines the Amici States' sovereign

[16] *See, e.g.*, Cal. Ins. Code § 10133.13.

authority in protecting the health and safety of our residents.

II. DOJ Adopts an Overly Expansive—and Unprecedented—Interpretation of the FDCA.

DOJ justifies its subpoena through a novel and unreasonable interpretation of the FDCA. Contrary to established practice and precedent,[17] DOJ now interprets the FDCA to regulate the practice of medicine. It does so by sweeping into the statute's prohibitions, 21 U.S.C. § 331(a), (d), the routine administration of approved drugs for off-label purposes and communication between providers and patients about those drugs—medical practices and elements of the doctor-patient relationship that long-settled law says the Act does not touch. The implications of this reading are enormous: Far from being limited to the narrow space of gender-affirming care, DOJ's interpretation of the FDCA will have widespread and disastrous implications across the field of medicine (with particularly significant harms in some critical areas of care, such as pediatrics and oncology, where off-label use is especially prevalent) and could actively discourage open communication between health care providers and their patients about the medications they receive.

A. Off-label use of approved drugs where medically appropriate is permissible under the FDCA.

As part of its regulatory authority, the FDA may approve prescription drugs to be marketed and labeled for certain uses. Within the FDA, the Center for Drug Evaluation and Research (CDER) evaluates prescription drugs' safety and efficacy through premarket approval.[18] Premarket approval is a multi-step process (involving multiple applications and

[17] *Ass'n of Am. Physicians & Surgeons v. U.S. Food & Drug Admin.*, 13 F.4th 531, 534 (6th Cir. 2021) (citing *Buckman.*, 531 U.S. at 350-51) ("Although the Act regulates a manufacturer's distribution of drugs, it does not go further by regulating a doctor's practice of medicine.").

[18] Ryan Abbott & Ian Ayres, *Evidence and Extrapolation: Mechanisms for Regulating Off-Label Uses of Drugs and Devices*, 64 Duke L.J. 377, 383 (2014).

stepped authorizations) that ultimately results in approval of a drug to be marketed and sold for a particular indication (use) in a specific population.[19] The FDA's approval also includes an approved drug label, which is "a summary of the evidence supporting the safe and effective use of the drug."[20]

The process by which the FDA approves drugs for particular indications is "not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient" and instead "is intended to ensure that drugs meet certain statutory standards for safety and effectiveness, manufacturing and controls, and labeling[.]" *Weaver v. Reagen*, 886 F.3d 194, 198 (8th Cir. 1989). Consequently, it is well-settled that "[a]s a general matter, once a drug is approved, physicians may *prescribe* the drug without restriction."[21] The FDA itself has repeatedly made public statements to this effect,[22] including as recently as this year,[23] and its own website specifically says that once the agency "approves a drug, health care providers generally may prescribe the drug for unapproved use when they judge that it is medically appropriate for their patient."[24] Courts also routinely recognize that the

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[19] Abbott & Ayres, *supra* note 18, at 384.

[20] Abbott & Ayres, *supra* note 18, at 384-85.

[21] Abbott & Ayres, *supra* note 18, at 387 (2014); *see also Buckman*, 531 U.S. at 350 (explaining that "off-label" use of medical *devices* "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine").

[22] *See, e.g.*, Abbott & Ayres, *supra*, at 387 n.32 (quoting *Promotion of Unapproved Drugs and Medical Devices, Testimony Before e the S. Comm. on Labor and Human Res.*, 104th Cong. (1996) (statement of William B. Schultz, Deputy Comm'r for Policy, Food & Drug Admin.) ("The legislative history of the Federal Food, Drug, and Cosmetic Act indicates that Congress did not intend FDA to interfere with the practice of medicine. Thus, once a drug is approved for marketing, FDA does not generally regulate how, and for what uses, physicians prescribe that drug. A physician may prescribe a drug for uses or in treatment regimens or patient populations that are not listed in the FDA-approved labeling.").

[23] *See* FDA, *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products; Questions and Answers; Guidance for Industry* 8-9 (Jan. 2025), https://www.fda.gov/media/184871/download (acknowledging various circumstances in which health care providers may validly prescribe drugs for off-label use).

[24] FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

FDCA permits doctors to prescribe medications off label. *See, e.g.*, *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 541 F. Supp. 3d 164, 173 (D. Mass. 2021), *aff'd*, 57 F.4th 327 (1st Cir. 2023) ("It is generally lawful for physicians to prescribe medications for purposes for which they have not been FDA-approved."); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) ("Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses."); *Wash. Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."). And DOJ's own Office of Legal Counsel (OLC) concurs, writing that "[a]s a general matter, [the] FDA does not regulate the practice of medicine, which includes 'off-label' prescribing."[25] As a result, off-label usage of drugs and devices is an important part of the practice of medicine, particularly in certain fields like pediatrics and oncology. *See infra* Part II.C.

B. DOJ wrongly sweeps off-label prescribing and dispensing into the FDCA's prohibitions concerning distribution and promotion of unapproved drugs.

DOJ admits, as it must, that physicians "are permitted to prescribe an FDA-approved drug for an unapproved use." Hsiao Decl. ¶ 12. Recognizing this limitation, DOJ instead improperly characterizes the lawful practice of a clinician prescribing and communicating about FDA-approved drugs for off-label uses as violations of the FDCA's prohibitions concerning the *distribution* and *labeling* of drugs for unapproved uses. DOJ's reading of the FDCA is wrong, has no basis in law, and, if adopted, will have broad implications far beyond the administration of gender-affirming care.

[25] Steven A. Engel, *Whether the Food & Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (2019).

1. Purchasing, storing, and administering approved medications does not give rise to criminal liability under the FDCA.

DOJ wrongly claims, without support, that the FDCA subjects hospital staff and medical providers to criminal liability when they purchase, store, and administer an approved drug for a purpose other than that approved by the FDA. To get to that conclusion, DOJ offers an elaborate, multi-step interpretation of the FDCA, which would (for the first time) make providers criminally liable for purchasing, storing, and administering a drug for an off-label use. It says, *first,* that "introducing a 'new drug' into interstate commerce without an FDA-approved indication is unlawful," Hsiao Decl. ¶ 22; *second*, that since drugs used to treat gender dysphoria in minors have not been specifically approved for that indication, "[those drugs] constitute unapproved new drugs under federal law," *id.*; *third*, that "distribution for that unapproved indication violates the FDCA and is a federal crime," *id.*; and *finally*, that health care providers who "purchase, store, and administer the drug … [are] in the chain of distribution of that drug," *id.* ¶ 23. The government's tortured analysis is at odds with explicit statutory language as well as accepted practice and precedent, and would make hospital pharmacies, hospital departments, and even retail pharmacies liable for routine parts of their practice.

The specific drugs highlighted by DOJ as potentially exposing providers to criminal liability are puberty blockers, which are "typically implants or injectables," Hsiao Decl. ¶ 23, that are administered by medical providers at their offices. Implanted puberty blockers are devices under 21 U.S.C. § 321(h)(1), which the FDCA explicitly allows providers to administer to patients for off-label uses. *See* 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). Contrary to DOJ's interpretation, providers who are

purchasing, storing, and administering such implants or injectables for an off-label use in their places of practice are thus not unlawfully "distributing" the drug or device, *see* Hsiao Decl. ¶ 23, within the meaning of the FDCA. The suggestion that FDCA liability attaches to anyone who administers an approved device for an unapproved but medically indicated purpose is thus belied by the statutory framework. *See* 21 U.S.C. § 396.

Moreover, the prescription or administration of an approved medication or device off label by a medical provider does not render it a "new drug" for purposes of the FDCA, or render it "unapproved." Rather, it is well established that "medical professionals may lawfully prescribe and administer a device for an off-label use as long as that device has received [FDA] clearance for any intended use." *United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023), cert. denied, 145 S. Ct. 137 (2024). If this were not so, virtually all drugs in common use across the United States would be deemed in violation of the statute if prescribed for any purpose other than what is specified on the label.

Finally, the idea that a provider becomes an unlawful "distributor" if the provider purchases, stores, and administers a drug to a patient is in tension with the widely accepted and permissible off-label dispensing of drugs. Providers regularly purchase, store, and administer drugs for off-label uses in hospital settings, residential facilities like nursing homes or rehabilitation centers, and certain outpatient treatment centers because such treatment is medically appropriate. Indeed, this interpretation would virtually upend oncology practices, where the purchase, storage, and on-site administration of chemotherapeutic drugs for off-label uses is not only extremely common but also recognized as vital by CMS.[26] DOJ's misplaced

[26] Coleen Klasmeier, *FDA, Medical Communications, and Intended Use-A New Challenge to First and Fifth Amendment Constraints on Government Power*, 78 Food & Drug L.J. 263, 271 (2023); *see* CMS, *Article: Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen* (rev'd Nov. 16, 2023), https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58113.

theory of provider liability would endanger these routine and widespread methods of care and would effectively nullify the longstanding recognition of the propriety and legality of off-label prescribing by duly licensed medical professionals. *See, e.g., In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019) ("The FDCA . . . does not prohibit doctors from prescribing drugs for off-label uses."). Indeed, the DOJ OLC has noted that the FDCA's prohibitions on distribution generally are not applicable to providers, observing that "[w]hile the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses."[27]

2. Practitioners' provision of information about off-label uses does not subject medical providers to liability for misbranding.

Under the FDCA, a drug or device is deemed "misbranded" if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1). The FDCA statutory framework bars the introduction or delivery for introduction into interstate commerce of any food, drug, device…that is adulterated or misbranded." 21 U.S.C. § 331(a). Previously, the FDA has construed § 331(a) in the context of misbranding or mislabeling as applying to "firms," *i.e.*, pharmaceutical companies, or their paid consultants—not to unaffiliated health care providers.[28]

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[27] Engel, *supra* note 25, at 85.

[28] *See, e.g.,* FDA, *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products; Questions and Answers; Guidance for Industry* 8-9 (Jan. 2025), https://www.fda.gov/media/184871/download (acknowledging various circumstances in which health care providers may validly prescribe drugs for off-label use). (Note that although this guidance is final, it is "not for current implementation," as it is currently before the Office of Management and Budget for approval of information collection provisions. *See id*. at 29.) Moreover, even in circumstances involving paid promotional activity (which is, again, not at issue here), where the "communications" between the pharmaceutical company and provider are truthful, the FDA has recognized that there are First Amendment constraints on their ability to charge such communications as "misbranding." *See, e.g.*, FDA, *Addendum to Jan 2017 FDA Memo—Additional and Updated Considerations Related to Manufacturer Communications Re Unapproved Uses of Approved or Cleared Medical Products* (Jan. 2025), https://www.regulations.gov/document/FDA-2016-N-1149-0107.

Yet in its Motion and the accompanying Hsiao Declaration, DOJ suggests that medical providers could be liable under the FDCA's prohibition on distributing "misbranded" medications merely for explaining an off-label use of an already-approved drug or device to patients. *See* Hsiao Decl. ¶¶ 13-16. DOJ observes that the FDCA defines labeling broadly to include material that "supplements, explains, or is designed for use with the drug," including things like flyers or instruction sheets. *Id.* ¶ 15. It then extrapolates that if a person "distributes (or causes the distribution of) an approved drug with false or misleading labeling for an unapproved use, [they] could possibly be charged with misbranding the drug or distributing a misbranded drug." *Id.* ¶ 16. Together with its assertion that a medical provider who stores or administers such a drug is in the chain of distribution, DOJ's claim here thus implies that a doctor who provides her patient with an instruction sheet explaining the off-label drug she is administering could be subject to criminal liability for misbranding under the FDCA.[29]

The construction adopted by DOJ in this matter thus departs both from the typical conduct and typical actors usually considered to be within the scope of § 331(a). Such a construction appears to be a sharp departure from the federal government's own past practice. Amici are unaware of any instance when DOJ or FDA has extended liability to a practitioner in the circumstances here—that is, when, with no connection to any firm-supported promotional activity (such as paid peer-to-peer presentations), the practitioner merely prescribes and provides information about an off-label drug to a patient.

The implications of DOJ's adopted construction are considerable. Under this interpretation, if a provider consults with a patient, suggests off-label use of a medication, and

[29] In its briefing, DOJ specifically suggests that BCH's statements on its websites about the effects of puberty blockers "could be considered 'labeling' in certain circumstances, which could form the basis of [a] federal healthcare offense" under the FDCA. Br. 10.

provides the patient with materials explaining the off-label use of that medication, that provider could potentially have "distributed" a "misbranded" drug. Such a broadening of the scope of the FDCA inserts the government into the exam room to regulate conversations between providers and their patients about possible treatment options. Not only does this have implications for the efficacy of care a medical professional can provide, it also inhibits a patient's ability to fully understand and give informed consent to certain procedures and medications prescribed off label.

C. DOJ's expansive interpretation of the FDCA jeopardizes entire fields of medicine.

DOJ's baseless interpretation of the FDCA—that off-label administration of a drug can constitute unlawful distribution, and providing instructions for an off-label drug can constitute unlawful branding—would have devastating and far-reaching effects that go far beyond the narrow field of gender-affirming care. Recent estimates suggest that between 20 and 50 percent of all prescriptions are for off-label indications.[30] Further, providers in all medical fields regularly purchase and administer drugs at their place of practice: in hospitals, where providers dispense medication in emergency departments, inpatient units, and oncology units; in residential facilities like nursing homes or rehabilitation centers for eating disorders; or in certain outpatient treatment centers. And as discussed above, in the case of medical devices that must be implanted or inserted by medical professionals, such as chemotherapy ports, knee replacements, or indeed any surgical device, those are necessarily purchased and stored on-site. DOJ's interpretation of the FDCA would lead to sweeping criminalization of providers in all these settings who purchase, store, prescribe, dispense, and explain medication to patients for routine off-label use.

Furthermore, "the prescription of drugs for unapproved uses … is *ubiquitous* in certain

[30] James M. Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 UIC J. Marshall L. Rev. 1, 25 & n.112 (2021).

specialties." *Wash. Legal Foundation*, 202 F.3d at 333 (emphasis added). To give one example, providers in oncology units very commonly administer a variety of cancer treatments off label, as several cancer-treating medications are effective for more than one type of cancer, and providers often employ combination chemotherapy.[31] As a result, some scholars estimate that 50 to 75 percent of drug use in oncology settings occurs off label.[32] Over time, other fields where off-label use of drugs and medical devices has been particularly prominent have included heart and circulatory disease, AIDS, kidney disease requiring dialysis, osteoporosis, spinal fusion surgery, rare diseases, and psychiatry.[33]

Saliently to the dispute now before this Court, one area where off-label prescribing is especially widespread is pediatrics. Data on the effects of drugs on children is less available than for adults for a variety of reasons, "including unfamiliarity with age-related developmental pharmacology in pediatric patients, ethical considerations with conducting pediatric research, and a lack of financial incentive for the pharmaceutical industry."[34] This lack of data in turn drives a relative paucity of FDA approvals of drugs for pediatric indications[35]—indeed, many drugs carry a so-called "orphaning clause" disclaimer as to pediatric use in light of the absence of sufficient studies.[36] Consequently, some studies estimate that as much as 80 percent of drugs

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[31] *See Nat'l Cancer Inst., Off-Label Drug Use in Cancer Treatment* (rev'd Jan. 13, 2022), https://www.cancer.gov/about-cancer/treatment/drugs/off-label.

[32] Beck, *supra* note 30, at 25-26 & n.113.

[33] James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L. J. 71, 80 (1998).

[34] H. Christine Allen et al., *Off-Label Medication Use in Children, More Common than We Think: A Systematic Review of the Literature*, 111 J. Okla. St. Med. Ass'n 776, 777 (2018); *see also* FDA, *Pediatric Ethics* (rev'd Jan. 16, 2024), https://www.fda.gov/science-research/pediatrics/pediatric-ethics; FDA, *Additional Protections for Children* (rev'd Sept. 21, 2015), https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/additional-protections-children.

[35] Lewis A. Grossman, *Criminalizing Transgender Care*, 110 Iowa L. Rev. 281, 310 (2024).

[36] Beck & Azari, *supra* note 33, at 80 n.81.

prescribed for children are prescribed for off-label uses.[37]

DOJ's groundless attempt to shoehorn routine parts of the off-label prescription and administration of medications into the FDCA's criminal prohibitions in pursuit of its stated goal of "ending" gender-affirming care, Br. 11, threatens an enormous range of medical care in a wide variety of fields. While this subpoena is concerned with gender-affirming care for adolescents, nothing about DOJ's interpretation of the FDCA offers any kind of limiting principle that would cabin its criminalizing effect. Rather, DOJ's efforts to apply the FDCA's criminal provisions concerning distribution and branding to routine off-label prescribing jeopardizes the availability of medical care for many who need it the most.

The implications and consequences of adopting DOJ's interpretation of the FDCA are even more dire considering the DOJ's allusions to strict criminal liability. As DOJ notes, the violation of 21 U.S.C. § 331—the criminal provision of the FDCA that, among other things, addresses the distribution and labeling of drugs and medical devices—"is punished as a strict liability misdemeanor without any proof of criminal intent." Hsiao Decl. ¶ 19 (citing *U.S. v. Park*, 421 U.S. 658, 672-73 (1975)). Under what is referred to as the *Park* doctrine, this liability is extended to corporate officers. *Park*, 421 U.S. at 672-73. In addressing the particulars of its subpoena to BCH, DOJ in turn references those same strict liability provisions as justifying its request for information on the personnel at BCH responsible for the direction of prescribing and marketing practices. Hsiao Decl. ¶ 40. The implication is clear: under DOJ's read of the FDCA and the *Park* doctrine, it intends to hold hospital administrators, doctors, and other providers strictly liable for perceived criminal violations of the statute.[38]

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[37] Beck, *supra* note 30, at 25-26 & n.114.

[38] Indeed, some critics of the *Park* doctrine "have suggested that the concept of liability for chief executives may become merely a 'hostage' rule under which criminal sanctions against individual executives are used as leverage to

Read together with its expansive view of the distribution and labeling provisions of the FDCA, DOJ's invocation of the *Park* doctrine reflects a shocking threat: the federal government aims to prosecute medical providers and hospital administrators for federal crimes based on their routine prescription and administration of medication and communication with patients about the treatments they are receiving. Even the threat of such prosecution flatly contradicts the well-settled notion that the FDCA does not exist to regulate doctors' practice of medicine, *see, e.g.*, *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 534, and promises to have profound effects on the provision of health care across the country. The effects would be devastating, particularly in states like Massachusetts that see significant economic activity from the health care, biotech, and life sciences industries. This Court should reject DOJ's efforts to use the cudgel of criminal liability to intimidate the doctors and administrators who care for our communities.

CONCLUSION

For the foregoing reasons, Amici States respectfully encourage the Court to deny DOJ's motion to alter or amend the judgment quashing the subpoena directed to Boston Children's Hospital.

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exact strict compliance with FDA requirements with a minimal expenditure of government resources." James T. O'Reilly & Katherine A. Van Tassel, eds., 1 *Food and Drug Admin.* § 8:4 (4th ed.) (Westlaw Nov. 2023 update); *see also id.* at § 8:5 (discussing doctrine's "potential for abuse, using criminal threats as leverage to demand extrastatutory remedies").

Dated: October 21, 2025

/s/ Adam M. Cambier

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EXHIBIT 11

DECLARATION OF LISA K. HSIAO

Pursuant to 28 U.S.C. § 1746, I, Lisa K. Hsiao, hereby declare as follows:

GENERAL BACKGROUND

1. I am the Acting Director of the Consumer Protection Branch within the United States Department of Justice.

2. The Consumer Protection Branch ("CPB") handles criminal and civil litigation and related matters arising under federal statutes that protect consumers' health, safety, economic security, and identity integrity. The Branch is responsible for criminal and civil actions under statutes administered by the Food and Drug Administration. The Consumer Protection Branch (CPB) is authorized to oversee and conduct all civil and criminal matters arising under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, et seq. See 28 C.F.R. § 0.45(i) and Justice Manual 4-8.000.

3. Through Presidentially-appointed, Senate-confirmed officers of the Department of Justice, the Consumer Protection Branch is authorized to undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act (FDCA) relating to the on- or off-label use by manufacturers and distributors of drugs, including puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called "gender transition." See AG Bondi Memo dated April 22, 2025.

4. The Attorney General may authorize other officers of the Department of Justice to perform certain functions of the Attorney General. See 28 U.S.C. § 510. In any investigation of a federal health care offense, the Attorney General may issue in writing and cause to be served a

subpoena requiring the production and testimony described in 18 U.S.C. § 3486(a)(l)(B). See 18 U.S.C.§ 3486(a)(l)(A).

5. Pursuant to Attorney General Order Number 3591-2015, dated November 10, 2015, the Attorney General authorized the Assistant Attorney General for the Civil Division to issue and serve administrative subpoenas pursuant to 18 U.S.C. §§ 3486(a)(l)(A) and (a)(l)(B) to investigate violations of the FDCA that relate to a health care benefit program.

6. The subpoena to University of Pittsburgh Medical Center, Children's Hospital of Pittsburgh ("UPMC"), No. 25-1431-031 was lawfully issued and authorized by Brett A. Shumate, Assistant Attorney General for the Civil Division, in connection with a valid investigation being conducted in my office.

7. The facts in this Declaration come from my personal observations, my training and experience, and information obtained from other government personnel. This Declaration is intended to demonstrate that the administrative subpoena discussed herein was issued in the furtherance of an investigation authorized by law, and that the records and other things the subpoena seeks are relevant to that investigation. Accordingly, this Declaration does not set forth all my knowledge about this matter.

LEGAL BACKGROUND

8. The overriding purpose of the FDCA is to protect the public health. *United States v. Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The FDCA's purpose should "infuse construction of the [FDCA]" so that courts give the FDCA a liberal construction that furthers protection of the public health, including in criminal enforcement of the FDCA. *Id. United States v. Dotterweich*, 320 U.S. 277, 280 (1943); *See also United States v. Park*, 421 U.S. 658, 672–73

(1975). This consideration applies even more strongly where the Government seeks to enforce the FDCA to protect the health of children.

9. A "Federal healthcare offense" for purposes of a subpoena issued under 18 U.S.C. § 3486 is defined by 18 U.S.C. § 24(a) as "a violation of, or a criminal conspiracy to violate … section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331) … if the violation or conspiracy relates to a health benefit program." 18 U.S.C. § 24(a). The statute defines "health care benefit program" to mean "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." 18 U.S.C. § 24(b). A subpoena issued under section 3486 (commonly referred to as a "HIPAA subpoena") may be used to investigate both substantive violations of the FDCA, as well as conspiracies to violate the FDCA if the violation or conspiracy relates to products or services that might ultimately be paid for by a private or public health insurance program.

10. Administrative subpoenas issued under 18 U.S.C. § 3486 are routinely used to obtain categories of medical, billing, and related information in federal healthcare offense investigations. The materials requested by the subpoenas issued in this investigation fall within that framework and include the same kinds of records—patient files, insurance submissions, treatment documentation, and communications (such as emails)—that federal investigators typically review to determine whether a federal health care offense may have occurred.

FDA'S APPROVAL OF DRUGS

11. The FDCA regulates the development, manufacturing and distribution of drugs in the United States. For a "new drug" to enter interstate commerce, the manufacturer must first

demonstrate to the United States Food and Drug Administration ("FDA") that the drug is both safe and effective for each of its intended uses. 21 U.S.C. §§ 331(d), 355(a). The introduction into interstate commerce of an unapproved new drug violates the FDCA. 21 U.S.C. § 331(d).

12. A drug manufacturer obtains FDA approval for a new drug through a new drug application ("NDA") that demonstrates that its drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a). As part of the approval process, FDA reviews the proposed labeling for the drug in the NDA, which must include adequate directions for how to use the drug for each of its intended uses. 21 U.S.C. § 352(f); 21 C.F.R. § 201.5. When FDA approves an NDA, it determines that the drug is safe and effective **for the specific use or uses identified in the application.** As part of that approval, FDA also approves the product's proposed labeling, including prescribing information, as providing adequate directions for use for those approved indications. FDA's approval of a drug for one or more particular uses does **not** mean that the drug is safe and effective for unapproved uses, nor does approval mean that the labeling provides adequate directions for unapproved uses. While physicians are permitted to prescribe an FDA-approved drug for an unapproved use, such prescribing may warrant investigation because it may provide evidence of FDCA violations. Also, depending on the circumstances, prescribing for unapproved uses can itself involve FDCA violations—for example, where the physician is engaged in the distribution or labeling of an unapproved drug.

MISBRANDING OF DRUGS PRESCRIBED FOR UNAPPROVED USES THROUGH ILLEGAL LABELING

13. A drug is misbranded if its labeling does not have adequate directions for the use of the drug. 21 U.S.C. § 352(f). FDA-approved labeling contains directions only for the drug's approved uses. If a drug manufacturer or other person distributes an approved drug for an unapproved use, the manufacturer or other person could be charged with misbranding the drug or distributing a misbranded drug with labeling that lacks adequate directions for its intended uses.[1]

[1] As noted above, it is possible for doctors to prescribe an approved drug for an unapproved use without violating the FDCA.

21 U.S.C. §§ 331(a), 331(b), 331(c), 331(k), and 352(f)(1). CPB has participated in successful prosecutions of drug manufacturers for such illegal conduct. *See, e.g.*, *United States v. Pharmacia & Upjohn Co.*, Case No. 09-CR-10258-DPW (D. Mass. 2009); *United States v. Eli Lilly & Co.*, Case No. 09-CR-00020-RK (E.D. Pa. 2009).

14. A drug is also misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

15. Under the FDCA, drug labeling is broadly defined as any "written, printed, or graphic matter … *accompanying*" the drug. 21 U.S.C. § 321(m) (emphasis added). The term "accompanying" is interpreted broadly and includes materials that are separate from the drug but nonetheless related to it, including any material that supplements, explains, or is designed for use with the drug. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 1.3(a); *Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948); *United States v. 47 Bottles … Jenasol RJ Formula 60*, 320 F.2d 564, 569 (3d Cir. 1963) (literature shipped by company to sales agent and then stored in agent's bedroom closet was labeling: "[I]t cannot be said that …the Court promulgated or intended to promulgate a requirement that there be an actual use in order that the literature constitute labeling."). Labeling can include promotional materials, advertisements, brochures, flyers, instruction sheets, posters, and similar materials.

16. If a drug manufacturer or other person distributes (or causes the distribution of) an approved drug with false or misleading labeling for an unapproved use, the manufacturer or other person could possibly be charged with misbranding the drug or distributing a misbranded drug. 21 U.S.C. §§ 331(a), 331(b), 331(c), 331(k), and 352(a). CPB has participated in successful prosecutions of manufacturers for false and misleading labeling. *See, e.g., United States v. Avanos Medical, Inc.*, Case No. 21-CR-0307-E (N.D. Tex. 2021) (deferred prosecution agreement for false and misleading labeling for medical device).

ILLEGAL DISTRIBUTION OF AN UNAPPROVED NEW DRUG

17. A "new drug" is any drug that is "not generally recognized, among [qualified] experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the *labeling* thereof … ." 21 U.S.C. § 321(p)(1) (emphasis added). Even if a substance has been on the market for years, it can be a "new drug" if used for an indication that has not been approved by FDA and is not generally recognized as safe and effective for that indication. The vast majority of prescription drugs on the market are "new drugs" under the FDCA.

18. If a drug manufacturer or other person distributes (or causes the distribution of) an approved drug for an unapproved use with labeling for that unapproved use, the manufacturer or other person could be charged with distributing an unapproved new drug in violation of the FDCA. 21 U.S.C. § 331(d).

INTENT IN FDCA CRIMES

19. A violation of 21 U.S.C. § 331 is a federal criminal offense that is punished as a strict liability misdemeanor without any proof of criminal intent. *See Park*, 421 U.S. at 672–73; *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). Through its strict liability misdemeanor provision, the FDCA imposes rigorous criminal accountability on companies and individuals involved with drugs that affect the health of consumers in circumstances where consumers realistically cannot protect themselves. *See Weisenfeld*, 376 U.S. at 91; *Dotterweich*, 320 U.S. at 280–81. This heightened accountability is even more acute when the consumers at risk are children. Consequently, any violation of Section 331, including the causing of any prohibited act listed in Section 331, is a federal crime, even in the absence of any criminal intent.

20. A felony FDCA violation requires the same conduct as the strict liability misdemeanor, but with the added element of an intent to defraud or mislead. 21 U.S.C. § 333(a). Evidence of intent to defraud or mislead—whether directed at a government agency, a patient, or an insurance company—thus transforms a misdemeanor FDCA violation into a felony offense. Evidence of an intent to defraud or mislead a government agency or another third-party, such as a patient or insurer, in connection with an FDCA violation is sufficient to establish a felony

FDCA offense. Efforts to conceal a violation or evade detection also can demonstrate the requisite intent to defraud or mislead.

THE DRUGS AT ISSUE IN THIS INVESTIGATION

21. This investigation focuses on prescription drugs typically used in gender-related care for children and adolescents suffering from a recognized mental disorder known as gender identity disorder or, as the most recent version of the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS refers to it, gender dysphoria. Included in this group of prescription drugs are (1) drugs used to suppress the production of sex hormones to delay puberty—the most common being gonadotropin-releasing hormone agonists ("GnRH agonists"), commonly referred to as "puberty blockers;" and (2) cross-sex hormones meant to induce physical changes to alter the child's secondary sexual characteristics to resemble those typically seen in the opposite sex and less like the individual's biological sex. Testosterone, a Schedule III controlled substance under the Controlled Substances Act, is included in this latter group.

22. FDA has not determined these drugs to be either safe or effective for the treatment of gender dysphoria. Nor has FDA approved any of these drugs for the treatment of gender dysphoria or any other psychiatric disorder. While these prescription drugs are FDA-approved for other indications (e.g., precocious puberty, prostate cancer, hypogonadism, etc.), FDA has not approved any NDA that establishes the safety and efficacy of these drugs for use in minors with gender dysphoria. As explained above, introducing a such "new drug" into interstate commerce without an FDA-approved indication is unlawful. Thus, to the extent these drugs are intended to treat gender dysphoria in minors, they constitute unapproved new drugs under federal law, and their distribution for that unapproved indication violates the FDCA and is a federal crime.

23. Some of these drugs, including puberty blockers, are not administered orally. Rather, they are typically administered by injection by a medical professional or through an outpatient surgical procedure to implant the drug. Puberty blockers are typically implants or injectables that require administration by a physician or nurse in a medical facility that must purchase, store, and administer the drug, placing healthcare providers in the chain of distribution of that drug. Similarly, testosterone may be, and often is, administered by injection.

24. The United States Government is aware of credible, publicly available evidence relating to the widespread practice of prescribing cross-sex hormones and puberty blockers to treat gender dysphoria in minors that casts doubt on the safety and efficacy of this practice. The United States Department of Health and Human Services ("HHS"), of which FDA is a component agency, has determined that the evidence for the safety and efficacy of these drugs for the treatment of gender dysphoria in minors is weak. *See generally*, U.S. DEP'T OF HEALTH & HUMAN SVCS., TREATMENT FOR PEDIATRIC GENDER DYSPHORIA, REVIEW OF EVIDENCE AND BEST PRACTICES (May 2025) (available at https://opa.hhs.gov/gender-dysphoria-report) ("HHS Report"). Specifically, this report found that some of the pharmacologic interventions under investigation here "carry risk of significant harms including infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, [and] psychiatric disorders." *Id.* at 10. HHS further determined that "the overall quality of [scientific] evidence concerning the effects of any intervention on psychological outcomes, quality of life, regret, or long-term health is **very low**." *Id.* at 13 (emphasis added).

25. The Government is also aware of other major scientific publications and national health authorities that have questioned the strength and quality of the evidence base for the

efficacy of puberty blockers and other medical interventions to treat youth for gender dysphoria. In the United Kingdom, for example, the British National Health Service ("NHS") commissioned an independent review led by Dr. Hilary Cass, a pediatrician and the former President of the Royal College of Paediatrics and Child Health, to evaluate how NHS was providing care for children experiencing gender-related distress. *See generally* NHS England, *Independent Review of Gender Identity Services for Children and Young People: Final Report* (Apr. 10, 2024), *available at* https://cass.independent-review.uk/home/publications/final-report/ ("*Cass Review*"). Dr. Cass's review concluded: "This is an area of remarkably weak evidence, and yet results of studies are exaggerated or misrepresented by people on all sides of the debate to support their viewpoint. The reality is that we have no good evidence on the long-term outcomes of interventions to manage gender-related distress." *Cass Review* at 13.

26. With regard to puberty blockers, Dr, Cass reported that a systematic review conducted by the University of York "found no evidence that puberty blockers improve body image or dysphoria" while "a known side effect of puberty blockers on mood is that it may reduce psychological functioning." *Id.* at 179. With regard to cross-sex hormones, the *Cass Review* agreed with another systematic review that concluded that: "There is a lack of high-quality research assessing the outcomes of hormone interventions in adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health." *Id.* at 184.

27. As a result of the *Cass Review's* findings, in December 2024, the United Kingdom banned puberty blocker treatment for gender dysphoria. *See* Press Release, U.K. Department of

Health & Social Care, *Ban on Puberty Blockers to be Made Indefinite on Experts' Advice* (Dec. 11, 2024), https://www.gov.uk/government/ news/ban-on-puberty-blockers-to-be-made-indefinite-on-experts-advice (stating that "there is currently an unacceptable safety risk in the continued prescription of puberty blockers to children"). Press reports indicate that the U.K. is similarly considering banning cross-sex hormones for minors. *See* Alison Holt, *Cross-Sex Hormones for Under 18s Could be Restricted or Banned*, BBC News (May 22, 2025), https://www.bbc.com/news/articles/cg711xevd890.

28. Other European countries have likewise enacted restrictions on the use of these pharmacologic interventions for treating gender-related disorders in minors, or are considering them. *See, e.g., Sweden Puts Brakes on Treatments for Trans Minors*, FRANCE 24 (Aug. 2, 2023), https://www.france24.com/en/live-news/20230208-sweden-puts-brakes-on-treatments-for-trans-minors; Siobhan Harris, *Europe & the Puberty Blocker Debate*, MEDSCAPE MED. NEWS (Apr. 25, 2024), https://www.medscape.com/viewarticle/europe-and-puberty-blocker-debate-2024a1000831 (reporting on European countries' practices and findings including France's National Academy of Medicine recommendation that the "greatest reserve" be used in puberty blockers and/or hormones in children and adolescents; Sweden's conclusion that the risks of puberty blockers and hormones currently outweigh the potential benefits).

29. Both the HHS review and the UK's independent *Cass Review*—along with numerous other systematic reviews of the evidence that the Government is aware of—justify questioning the scientific foundation for prescribing puberty blockers and cross-sex hormones for minors as limited and potentially problematic. It is far from certain, therefore, that prescribing these drugs—that have not been approved by FDA for treating minors with gender-related disorders—

would ever be considered by the agency as safe and effective for that indication. To the contrary, the available public record suggests there is a serious potential for harm.

EVIDENCE OF FDCA AND HEALTH CARE FRAUD VIOLATIONS IN PEDIATRIC GENDER-RELATED CARE

30. From testimonies of public whistleblowers and leading national medical experts on the subject matter, the Government is aware of potential violations of federal law in connection with the provision of gender-related treatments for minors occurring at healthcare providers across the country.

31. This includes allegations and evidence of fraudulent billing practices to secure insurance coverage/payment. Such practices include, but are not limited to, providers (i) using the incorrect diagnosis and/or billing code (e.g., "endocrine disorder, unspecified" instead of "gender dysphoria" to prescribe cross-sex hormones, or "precocious puberty" instead of "gender dysphoria" to prescribe puberty blockers) because they know that certain insurance plans may not cover the off-label prescription of puberty blockers or cross-sex hormones for gender-related treatment[2]; (ii) changing or misrepresenting a patient's sex in the medical records and coding and billing for "endocrine imbalance," which is supported by accompanying bloodwork showing endocrine levels atypical of the incorrectly documented sex (but consistent with the patient's actual sex); and (iii) fraudulently making a gender dysphoria diagnosis where patients do not meet the DSM-5 diagnostic criteria, but the providers know that the carrier or plan will cover off-label prescription of cross-sex hormones or puberty blockers to treat gender dysphoria.

[2] In fact, one nonprofit organization has published guidance to health care providers advising them of "coding alternatives for trans healthcare," which detailed "codes that are commonly rejected by insurance providers" and "codes that are commonly accepted by insurance providers."

32. The Government also knows of evidence and allegations of many cases where providers failed to provide adequate labeling and to provide the information necessary to obtain informed consent, actively deceived patients and parents with false claims and statements regarding the drugs' effectiveness or alternatives, and misrepresented to minor patients and their parents the risks associated with and the science claimed to support taking the drugs described herein for gender dysphoria.

33. The Government has also reviewed evidence (including transcripts and video recordings) from national conferences on treating transgender patients, including minors, wherein presenters describe and encourage attendees to engage in the provision of purely patient-driven care (or "embodiment goals"), with little regard for gender dysphoria diagnoses, assessment, or clinical criteria. These recommendations include prescribing cross-sex hormones and puberty blockers to minors. The Government is concerned that such facially deficient care may be accompanied by facially deficient or misleading labelling.

THE SUBPOENA SPECIFICATIONS SEEK INFORMATION RELEVANT TO THE INVESTIGATION

34. The fifteen requests in the investigative HIPAA subpoena issued to UPMC seek to further the investigation described above. The requests can be broadly broken down into four main categories: (1) requests related to personnel and corporate oversight (Request 1); (2) requests related to billing, coding, and reimbursement practices (Requests 2–6); (3) requests related to the practice's relationships with drug manufacturers, distributors, and pharmacies (Requests 7–10); and (4) requests regarding clinical practices and drug safety (Requests 11–15). All the subpoenaed records and documents are relevant to the federal healthcare investigation described herein. *See* 18 U.S.C. § 3486(a)(1).

35. Request 1 seeks information to identify who had authority to direct prescribing, billing, or marketing practices to determine liability. Under strict liability doctrines, including the responsible corporate officer doctrine, officers and responsible personnel can be held criminally liable for FDCA violations even without direct participation. Personnel files also show financial incentives, disciplinary history, and/or training which can establish knowledge and intent.

36. The requests in the second group (regarding billing, coding, and reimbursement practices) are necessary to determine whether the clinic disguised treatment for gender-related mental disorders as another, physical illness (*e.g.,* endocrine disorder) to secure health benefit program reimbursement. Such practices are especially important to demonstrate an "intent to defraud or mislead" under 21 U.S.C. § 333(a)(2) if the clinic misrepresented the intended use of the drugs. Moreover, training materials and internal discussions can reveal whether improper coding was a deliberate strategy.

37. The third group of requests (relating to relationships with drug manufacturers, distributors, and pharmacies) are probative of an intent to market or promote drugs for unapproved uses. If UPMC, or one of its affiliated healthcare providers, received promotional materials, "scientific exchange information," or payments to encourage prescribing of puberty blockers or cross-sex hormones, such information would support a FDCA theory (including conspiracy) involving unlawful off-label promotion. Similarly, information regarding financial arrangements (consulting agreements, sponsorships, speaking honoraria) may suggest improper influence to reinforce a showing an intent to misbrand, including with intent to defraud or mislead.

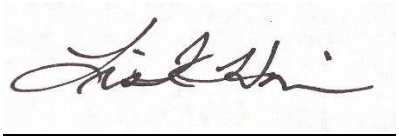
38. The final group of requests (relating to patient-level clinical practices and drug safety) will permit the United States to evaluate the scope of prescribing the drugs described herein

(including the number and age range of patients treated), and consistency of diagnoses. It also establishes the scope of interstate distribution and the scale of potential FDCA violations. Linking each patient's clinical record to corresponding billing and insurance claims can demonstrate whether diagnoses were miscoded, which can prove fraudulent intent. Documentation of clinical justification, informed consent, and disclosure of off-label use is key to assessing whether the clinic (and/or potential co-conspirators) concealed or downplayed risks associated with using these drugs in a manner not approved by FDA. Absence or minimization of such warnings could establish the intent to mislead. Patient charts also typically capture adverse outcomes, side effects, and complications of drug use. By reviewing multiple patient records, the investigative team may reveal systemic use of the same masking codes, fraudulent informed consent documents, etc. This enables investigators to distinguish between mere errors and an institutionalized practice. Finally, providing patient records, including patient identities, can provide essential investigative leads. Parents may be witnesses about what disclosures were made. Patients (depending on age and circumstances) may provide information about the informed consent process, side effects, or other false or misleading information about the drugs conveyed during treatment. Health benefit programs tied to identified patients could provide additional information, including claim records, creating a triangulated evidentiary record. In sum, without this information, the Government cannot fully determine the scope of the violations, identify patterns of misbranding or fraudulent billing, or assess whether the conduct was undertaken with intent to defraud or mislead, as required for felony liability under 21 U.S.C. § 333(a)(2).

GOVERNMENT INVESTIGATIVE RESOURCES

39. This is a bona fide, high-priority, and substantial national investigation of potential FDCA violations in the provision of gender-related care for minors. Substantial government resources have been assigned to it. It is being handled by several veteran, career prosecutors with many decades of experience in healthcare fraud and FDCA enforcement between them, supported by a team of document analysts and other forensic specialists. The Federal Bureau of Investigation has assigned agents and analysts to assist with various field activities and is employing advanced data analytics to identify prescribing patterns, potential unlawful off-label promotion, and patterns in reimbursement. The scope and coordination of these efforts reflect the seriousness with which the Government is pursuing potential violations of federal law.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 2nd day of October, 2025.



LISA K. HSIAO
Acting Director
Consumer Protection Branch
United States Department of Justice

EXHIBIT 12

United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In the Matter of Summons Numbers HSI-PH-2025-082814-001 and HSI-PH-2025-082819-001 Issued to Meta Platforms, Inc.:

J. Doe,

Movant,

v.

THE UNITED STATES DEPARTMENT OF HOMELAND SECURITY,

Respondent.

META PLATFORMS, Inc.

Third Party.

Case No. 25-mc-80325-PHK

ORDER RE: PENDING MOTION TO QUASH SUMMONSES ISSUED BY THE DEPARMENT OF HOMELAND SECURITY TO META PURSUANT TO 19 U.S.C. § 1509

Re: Dkt. 1

Movant J. Doe ("Doe") moves to quash two administrative summonses issued to Meta Platforms, Inc. ("Meta") on September 11, 2025 by the Department of Homeland Security pursuant to 19 U.S.C. § 1509. *See* Dkt. 1. The summonses at issue are designated as Summons Numbers HSI-PH-2025-082814-001 and HSI-PH-2025-082819-001. *See* Dkt. 1-3 (summons directed to Meta); Dkt. 1-4 (summons directed to Instagram). In sum, the summonses seek information on the identity of Doe, who has apparently posted information online (including allegedly political speech protected by the First Amendment) using anonymous Facebook and Instagram accounts. *See* Dkt. 1-3; Dkt. 1-4. The Motion to Quash asserts First Amendment and other legal bases for quashing the summonses.

In the Motion to Quash, Movant Doe "requests that this Court issue immediately an interim order directing Meta not to produce the information pending final resolution of this matter," because the production of the information sought would risk identifying Doe, thus depriving them of their asserted First Amendment right to post online using an anonymous account. [Dkt. 1 at 13 (collecting cases)]. This is not a theoretical risk, because according to Doe's sworn affidavit and Doe's counsel's representations under Rule 11: "Meta has committed to revealing its user's identity to DHS unless Movant seeks relief in court. Specifically, on October 3, 2025, Meta sent emails stating that it must 'receive a copy of documentation . . . challenging this legal process,' by October 13, 2025,25 or it 'will respond to the requesting agency with information about the requested [social media] account[s].'" *Id.* at 27 (quoting Dkt. 1-2 at ¶ 10).

The Court has broad discretion and authority to manage discovery. *U.S. Fidelity & Guar. Co. v. Lee Inv. LLC*, 641 F.3d 1126, 1136 n.10 (9th Cir. 2011) ("District courts have wide latitude in controlling discovery, and their rulings will not be overturned in the absence of a clear abuse of discretion."); *Laub v. U.S. Dep't of Int.*, 342 F.3d 1080, 1093 (9th Cir. 2003); *see also Crawford-El v. Britton*, 523 U.S. 574, 598 (1998) (holding trial courts have "broad discretion to tailor discovery narrowly and to dictate the sequence of discovery"). As part of its inherent discretion and authority, a district court also has discretion in resolving disputes over whether to grant a motion to compel compliance with or to quash a Rule 45 subpoena. *See Garrett v. City & Cnty. of S.F.*, 818 F.2d 1515, 1519 (9th Cir. 1987). Under Rule 81, Rule 45 applies to the administrative summonses at issue here because they were "issued by a United States officer or agency under a federal statute." *See* Fed. R. Civ. P. 81(a)(5).

Concomitant with the Court's discretion to manage discovery, courts have inherent authority and discretion to stay compliance with a subpoena (or administrative summons subject to Rule 45 via Rule 81) pending resolution of a motion testing that subpoena. *Harris v. United States*, 413 F.2d 314, 315 (9th Cir. 1969) (granting motion to stay compliance with a subpoena pending motion to quash and pending any appeal therefrom). The Ninth Circuit's stay order in *Harris* relies on the legal authority for courts to grant a stay of a discovery requests recognized by the Supreme Court in *Reisman*, which involved a challenge to an administrative summons issued

by the Internal Revenue Service (directly analogous to the summonses at issue here). *Id.* (citing *Reisman v. Caplin*, 375 U.S. 440, 445 (1964)). In particular, in *Reisman* the Supreme Court recognized that a party may intervene to challenge the propriety of the administrative summons at issue (which sought information regarding a particular witness), and the Supreme Court explicitly noted that "[i]t follows that with a stay order a witness would suffer no injury while testing the summons." *Reisman*, 375 U.S. at 449.

Accordingly, for all the reasons discussed herein, pending resolution of the Motion to Quash [Dkt. 1], the Court now **ORDERS** Meta (including its officers, directors, employees, agents, and those acting under the control of or in concert with Meta) not to produce any documents or information in response to the summonses at issue here without further order of the Court. This Order applies to both summonses at issue, and applies to Instagram (including Instagram's officers, directors, employees, agents, and those acting under the control of or in concert with Instagram) to the extent Instagram is a separate legal entity from Meta.

Counsel for Doe is **ORDERED** to promptly serve a copy of this Order on Meta and Instagram (to the extent Instagram is a separate legal entity from Meta) by any means reasonably calculated to provide notice. Counsel for Doe is further **ORDERED** to send with all deliberate speed a courtesy copy of this Order by email to counsel for Meta and for Instagram with whom counsel for Doe has been in communication regarding this matter, as reflected in the Motion to Quash. [Dkt. 1 at 27 n.25]. Counsel for Doe is further **ORDERED** to promptly serve a copy of this Order on counsel for Respondent and to send (with all deliberate speed) a courtesy copy by email to Respondent's counsel. Doe is **ORDERED** to file proofs of service for each party or third-party served.

IT IS SO ORDERED.

Dated: October 17, 2025

PETER H. KANG
United States Magistrate Judge

United States District Court
Northern District of California

EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: SUBPOENA NO. 25-1431-014	:	**MISCELLANEOUS ACTION**
	:	
	:	**NO. 25-39**
	:	
	:	**FILED UNDER SEAL**

ORDER

AND NOW, this 9th day of July 2025, upon considering Respondent's Motions to limit subpoena and seal (ECFs 1, 2), noting today is the return date on the subpoena, and finding good cause to allow responsive pleadings before ruling, it is **ORDERED** we:

1. **STAY** The Children's Hospital of Philadelphia's obligation to respond to the contested portions of the subpoena pending further Order;

2. **DIRECT** The Children's Hospital of Philadelphia to preserve all presently withheld subpoenaed information pending further Order;

3. **GRANT** the Department of Justice leave to respond to the pending Motion to seal (ECF 2) on or before **July 24, 2025,** and leave to respond to the pending Motion to limit (ECF 1) on or before **August 4, 2025;**

4. **DIRECT** counsel for The Children's Hospital of Pennsylvania to serve this Order via email upon counsel for the Department of Justice no later than **July 10, 2025** and file a certificate of service confirming compliance no later than **July 11, 2025.**

KEARNEY, J.